More than a product and a price.*
More than two decades of customized solutions and services.

As the world of specialty pharmaceuticals constantly expands, it is becoming more and more critical to have a partner you can truly depend upon to provide the drug and disease state knowledge and training you need, the accessibility you want and the unwavering service you require to deliver the best possible results for patients.

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For life’s critical moments...
TREATMENT SAFETY AND RELIABILITY MATTER TO US. CHOOSE HyperRHO® S/D (Rh₀[D] immune globulin [human])

HyperRHO® S/D Full Dose (Rh₀[D] immune globulin [human]) attributes:

- Established history – more than 40 years of consistent supply and product support
- 4-step virus removal and inactivation process
- The only Rh₀(D) immune globulin product with FDA labeling for prion removal
- Mercury (thimerosal) and latex free
- 36-month shelf-life
- Convenient low-volume fully assembled prefilled syringes
- Needle guards to protect against needlestick injury
- Tamper-evident packaging

HyperRHO S/D Full Dose is made from human plasma. Because this product is made from human plasma, it may carry a risk of transmitting infectious agents, such as viruses, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Please see Important Safety Information and brief summary of Prescribing Information for HyperRHO S/D Full Dose on preceding pages. Visit www.hypermunes.com for full prescribing information.
Reactions to RhO(D) immune globulin (human) are infrequent in RhO(D)-negative individuals and consist primarily of slight soreness at the site of injection. Failure to recognize this may result in the administration of an inadequate dose. Although systemic reactions to human immunoglobulin preparations are rare, epinephrine should be available for treatment of acute anaphylactic symptoms.

Administration of live virus vaccines (eg, MMR) should be deferred for approximately 3 months after RhO(D) immune globulin (human) administration. As with all preparations administered by the intramuscular route, bleeding complications may be encountered in patients with thrombocytopenia or other bleeding disorders.

A large fetomaternal hemorrhage late in pregnancy or following delivery may cause a weak mixed field positive D test result. If there is any doubt about the mother’s Rh type, she should be given Rh(D) immune globulin (human). A screening test to detect fetal red blood cells may be helpful in such cases.

Elevated bilirubin levels have been reported in some individuals receiving multiple doses of RhO(D) immune globulin (human) following neonatal transfusions. This is believed to be due to a relatively rapid rate of foreign red cell destruction.

Please see brief summary of full prescribing information on following page or visit www.hypermunes.com.

**HyperRHO® S/D Full Dose (RhO[D] immune globulin [human]) is indicated for the prevention of Rh hemolytic disease of the newborn by its administration to the RhO(D) negative mother within 72 hours after birth of an RhD positive infant, providing the following criteria are met: 1. The mother must be RhD negative and must not already be sensitized to the RhO(D) factor. 2. Her child must be RhD positive, and should have a negative direct antiglobulin test (see PRECAUTIONS).

**HyperRHO® S/D Full Dose should be administered intramuscularly. Never administer to the neonate.

**Early postpartum or antepartum transfusions and RhO(D) positive blood may have a weakly positive direct antiglobulin test at this time. It is recommended to administer RhO(D) Immune Globulin (Human) to women with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. The attending physician who wishes to administer RhO(D) Immune Globulin (Human) to pregnant women should be aware of the potential for hypersensitivity reactions. Such persons have increased potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA.

As with all preparations administered by the intramuscular route, bleeding complications may be encountered in patients with thrombocytopenia or other bleeding disorders.

**HyperRHO® S/D Full Dose should be given in pregnant women only if clearly needed because animal reproduction studies have not been conducted.

**RhO(D) Immune Globulin (Human) should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. Such persons have increased potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA.

As with all preparations administered by the intramuscular route, bleeding complications may be encountered in patients with thrombocytopenia or other bleeding disorders.

**HyperRHO® S/D Full Dose should be administered within 72 hours after birth or at the time of an RhD positive intrauterine abortion, if there is any doubt about the mother’s Rh type, she should be given RhO(D) immune globulin (human). A screening test to detect fetal red blood cells may be helpful in such cases.

**Elevated bilirubin levels have been reported in some individuals receiving multiple doses of RhO(D) immune globulin (human) following neonatal transfusions. This is believed to be due to a relatively rapid rate of foreign red cell destruction.

**Please see brief summary of full prescribing information on following page or visit www.hypermunes.com.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

**Please see brief summary of full prescribing information on following page or visit www.hypermunes.com.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
ALPHANATE®
Antihemophilic Factor/von Willebrand Factor Complex (Human)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ALPHANATE safely and effectively. See full prescribing information for ALPHANATE.

ALPHANATE (antihemophilic factor/von Willebrand factor complex [human])
Lyophilized Powder for Solution for Intravenous Injection
Initial U.S. Approval: 1978

--------------------------------------INDICATIONS AND USAGE--------------------------------------
ALPHANATE, (antihemophilic factor/von Willebrand factor complex [human]), is indicated for:
• Control and prevention of bleeding in adult and pediatric patients with hemophilia A.
• Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand Disease in whom desmopressin (DDAVP) is either ineffective or contraindicated. It is not indicated for patients with severe VWD (Type 3) undergoing major surgery.

--------------------------------------DOSAGE AND ADMINISTRATION--------------------------------------
For intravenous injection after reconstitution only.
ALPHANATE contains the labeled amount of factor VIII expressed in International Units (IU) FVIII/vial and von Willebrand Factor:Ristocetin Cofactor activity in IU VWF:RCo/vial.

**Dose**

**Treatment and Prevention of Bleeding Episodes and Excess Bleeding During and After Surgery in Patients with Hemophilia A**
• Dose (units) = body weight (kg) x desired FVIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL).
• Dosing frequency determined by the type of bleeding episode and the recommendation of the treating physician.

**Treatment and Prevention of Excess Bleeding During and After Surgery or Other Invasive Procedures in Patients with von Willebrand Disease**
• Adults: Pre-operative dose of 60 IU VWF:RCo/kg body weight; subsequent doses of 40-60 IU VWF:RCo/kg body weight.
• Pediatric: Pre-operative dose of 75 IU VWF:RCo/kg body weight; subsequent doses of 50-75 IU VWF:RCo/kg body weight.

--------------------------------------DOSAGE FORMS AND STRENGTHS--------------------------------------
ALPHANATE is available as a lyophilized powder for intravenous injection after reconstitution in single dose vials containing 250, 500, 1000, 1500 IU and 2000 IU FVIII.

--------------------------------------CONTRAINDICATIONS--------------------------------------
Do not use in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.

--------------------------------------WARNINGS AND PRECAUTIONS--------------------------------------
• Anaphylaxis and severe hypersensitivity reactions are possible. Discontinue treatment with ALPHANATE and administer appropriate emergency treatment should symptoms of anaphylaxis or severe hypersensitivity occur.
• Development of activity-neutralizing antibodies may occur in patients receiving FVIII containing products.
• Thromboembolic events (TE) may occur in VWD patients, especially with known risk factors. Monitor patients for signs and symptoms of TE.
• Intravascular hemolysis may occur with infusion of large doses of Antihemophilic Factor/von Willebrand Factor Complex. Should this condition occur and lead to progressive hemolytic anemia, discontinue administration of ALPHANATE and consider alternative therapy.
• Rapid administration may result in vasomotor reactions.
• ALPHANATE is made from human plasma and may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.
• Perform assays to determine if FVIII inhibitors are present.

--------------------------------------ADVERSE REACTIONS--------------------------------------
The most frequent adverse drug reactions reported with ALPHANATE in >1% of infusions were pruritus, headache, back pain, paresthesia, respiratory distress, facial edema, pain, rash and chills.

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Biologicals Inc. at 1-888-GRIFOLS (1-888-474-3657) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

--------------------------------------USE IN SPECIFIC POPULATIONS--------------------------------------
• Pregnancy: No human or animal data. Use only if clearly needed.
• Pediatric: Age had no effect on the pharmacokinetics of ALPHANATE.

GRIFOLS
Grifols Biologicals Inc.
5555 Valley Boulevard
Los Angeles, CA 90032, U.S.A.
U.S. License No. 1694

3042868-BS
Revised: 03/2015
Alphanate®
antihemophilic factor/von Willebrand factor complex (human)

THE NATURAL CHOICE

ALPHANATE is the #1 prescribed plasma-derived factor VIII product* and is preferred by hematologists practicing in HTCs for the treatment of hemophilia A.†

*Adapted from The plasma proteins market in the United States 2014. Revised 2015. Orange, CT: The Marketing Research Bureau, Inc.
†Results are statistically significant with a 95% confidence interval with a 6.5% margin of error and are based on a blinded/national survey of 75 HTC-based hematologists from a list of federally and non-federally funded HTCs within the US, conducted and validated by a reputable, independent third party, Adivo Associates LLC, on behalf of Grifols USA from October 2014 to January 2015. In order to qualify to complete the survey, hematologists were rigorously screened according to market research standards for having the necessary experience in the relevant treatment segment. Respondents were asked to assume no difference in terms of availability, cost, and reimbursement when indicating their most preferred plasma-derived FVIII brand.

HTC=Hemophilia Treatment Center.

Indications
ALPHANATE® (antihemophilic factor/von Willebrand factor complex [human]) is indicated for:
• Control and prevention of bleeding episodes and perioperative management in adult and pediatric patients with factor VIII (FVIII) deficiency due to hemophilia A
• Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand disease (VWD) in whom desmopressin (DDAVP) is either ineffective or contraindicated.
   It is not indicated for patients with severe VWD (type 3) undergoing major surgery

Important Safety Information
ALPHANATE is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.

Discontinue use of ALPHANATE if hypersensitivity symptoms occur, and initiate appropriate treatment.
Development of procoagulant activity-neutralizing antibodies (inhibitors) has been detected in patients receiving FVIII-containing products. Carefully monitor patients treated with AHF products for the development of FVIII inhibitors by appropriate clinical observations and laboratory tests.
Thromboembolic events have been reported with AHF/VWF complex (human) in VWD patients, especially in the setting of known risk factors.
Intravascular hemolysis may occur with infusion of large doses of AHF/VWF complex (human).
Rapid administration of a FVIII concentrate may result in vasomotor reactions.
Because ALPHANATE is made from human plasma, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite steps designed to reduce this risk.
Monitor for development of FVIII and VWF inhibitors. Perform appropriate assays to determine if FVIII and/or VWF inhibitor(s) are present if bleeding is not controlled with expected dose of ALPHANATE.
The most frequent adverse drug reactions reported with ALPHANATE in >1% of infusions were pruritus, headache, back pain, paresthesia, respiratory distress, facial edema, pain, rash, and chills.

Please see brief summary of ALPHANATE full Prescribing Information on adjacent page.
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
Learn more at alphanate.com

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Incremental recovery is defined as the increase in plasma concentration per IU/kg of factor administered.

Plasma-derived factor products have an incremental recovery close to 1, or 100%.\textsuperscript{1} Recombinant factor products have historically had an incremental recovery that is less than 100%.\textsuperscript{1,2}

**Recovery impacts your infusion volume.**

Think of it like this:

Recovery is a multiplier in the dosing calculation.

*The higher the recovery of a factor product, the lower the calculated dose and infusion volume.*

\[ \text{Dose (IU)} \times \text{Body weight (kg)} \times \frac{\% \text{ Desired factor IX increase}}{1 \text{ recovery multiplier}} = \]

*Individual dose may vary. Discuss your actual dose with your healthcare provider before adjusting it.*
The impact of recovery on infusion volumes.

Mike Rogers, an active guy in his 20s, runs and hits the gym several times a week. He infuses before workouts, weighs 165 lb (about 75 kg), and is looking for a 50% factor IX increase (correction).

If his factor has a higher recovery, his dose will be lower.*

His choice of a factor therapy: decisions tied to his recovery
- Knows that a factor with higher recovery could mean a lower dose.
- Understands that factor acts differently in each person’s body and individual recovery may vary.
- Likes that a lower dose may mean:
  — Lower infusion volumes
  — Fewer vials of factor needed for each infusion
  — Shorter infusion times so he can get back to his active life

How does the recovery of your factor impact your dose?
1. Do you know the recovery of your factor treatment?
2. Have you discussed with your doctor how your factor dose is calculated?
3. Have you had a PK test done to determine your individualized response to factor (eg, recovery, half-life, clearance)?

Discuss the recovery of your factor with your doctor, and see how it affects your infusion volume. Learn more at AptevoHemophilia.com


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The only unmodified, full length rFVIII offering the potential for as few as 2 infusions per week*.

INDICATIONS
KOVALTRY® Antihemophilic Factor (Recombinant) is a recombinant human DNA sequence derived, full length Factor VIII concentrate indicated for use in adults and children with hemophilia A for:
- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes
KOVALTRY® is not indicated for the treatment of von Willebrand disease.

SELECTED IMPORTANT SAFETY INFORMATION
KOVALTRY® is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, to any of the excipients, or to mouse or hamster proteins.

Please see additional Selected Important Safety Information on following pages. For additional important risk and use information, please see Brief Summary on following pages.

*Compared to other rFVIII products.

INDICATIONS
KOVALTRY® Antihemophilic Factor (Recombinant) is indicated for:
- On-demand treatment and control of bleeding episodes
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Please see additional Selected Important Safety Information on following pages. For additional important risk and use information, please see Brief Summary on following pages.

*Compared to other rFVIII products.
Designed with his future in mind

Proven efficacy and safety in adolescents and adults with prophylaxis using as few as 2 infusions per week

LEOPOLD I Trial

<table>
<thead>
<tr>
<th>Study description</th>
<th>Multinational, open-label, prospective trial evaluating pharmacokinetics, efficacy, safety, and perioperative management of bleeding with KOVALTRY®</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Previously treated male patients (PTPs) aged 12 to 65 years with severe hemophilia A (&lt;1% FVIII) [n=73] studied for 1 year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dosing</th>
<th>Dosing regimens were determined by the investigators to meet individual patients’ needs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2x/week prophylaxis: 20-50 IU/kg [n=18]</td>
</tr>
<tr>
<td></td>
<td>3x/week prophylaxis: 20-50 IU/kg [n=44]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary efficacy endpoint</th>
<th>Annualized bleed rate (ABR) at 12 months [n=62 for efficacy analysis]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>After a single 50 IU/kg dose of KOVALTRY®, the demonstrated half-life [mean ± standard deviation (SD)] in 26 previously treated adolescent and adult patients was:</td>
</tr>
<tr>
<td></td>
<td><strong>12 to 17 years</strong> (n=5)</td>
</tr>
<tr>
<td></td>
<td>Chromogenic Assay: 14.4 ± 5.5 hours</td>
</tr>
<tr>
<td></td>
<td>One-stage Assay: 11.7 ± 1.1 hours</td>
</tr>
<tr>
<td></td>
<td><strong>≥18 years</strong> (n=21)</td>
</tr>
<tr>
<td></td>
<td>Chromogenic Assay: 14.2 ± 3.5 hours</td>
</tr>
<tr>
<td></td>
<td>One-stage Assay: 14.3 ± 3.7 hours</td>
</tr>
</tbody>
</table>

**SELECTED IMPORTANT SAFETY INFORMATION**

- Hypersensitivity reactions, including anaphylaxis, are possible with KOVALTRY®. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea. Discontinue KOVALTRY® if symptoms occur and seek immediate emergency treatment.

- KOVALTRY® may contain trace amounts of mouse and hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.

Please see additional Important Safety Information on following pages. For additional important risk and use information, please see Brief Summary on following pages.
ABR by dosing regimen
Dosing was investigator determined to meet individual patients’ needs.1

Patients who generally began the study with fewer bleeds and a lower percentage of target joints were selected for
2x/week prophylaxis and experienced1,2

Patients who generally began the study with more bleeds and a higher percentage of target joints were selected for
3x/week prophylaxis and experienced1,2

87% of bleeding episodes resolved with ≤2 infusions of KOVALTRY®1

People with hemophilia A may develop inhibitors to rFVIII. People with a history of inhibitors were excluded from LEOPOLD I.1

SELECTED IMPORTANT SAFETY INFORMATION

Neutralizing antibody (inhibitor) formation can occur following administration of KOVALTRY®. Previously untreated patients (PUPs) are at greatest risk for inhibitor development with all Factor VIII products. Carefully monitor patients for the development of Factor VIII inhibitors, using appropriate clinical observations and laboratory tests. If expected plasma Factor VIII activity levels are not attained or if bleeding is not controlled as expected with administered dose, suspect the presence of an inhibitor.

People with hemophilia A may develop inhibitors to rFVIII. People with a history of inhibitors were excluded from LEOPOLD I.1

Median dose: 35.0 IU/kg (range: 21-42 IU/kg)
Median dose: 31.1 IU/kg (range: 24-43 IU/kg)

ABR by dosing regimen
Dosing was investigator determined to meet individual patients’ needs.1

Patients who generally began the study with fewer bleeds and a lower percentage of target joints were selected for
2x/week prophylaxis and experienced1,2

Patients who generally began the study with more bleeds and a higher percentage of target joints were selected for
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People with hemophilia A may develop inhibitors to rFVIII. People with a history of inhibitors were excluded from LEOPOLD I.1

Median dose: 35.0 IU/kg (range: 21-42 IU/kg)
Median dose: 31.1 IU/kg (range: 24-43 IU/kg)
Main image text:

**Opening the possibilities for your younger patients**

Proven efficacy and safety in previously treated children with prophylaxis using as few as 2 infusions per week ¹

**LEOPOLD Kids Trial—Part A¹**

### Study description
- Multinational, open-label, prospective trial evaluating the pharmacokinetics, efficacy, safety, and perioperative management of bleeding with KOVALTRY®
- Previously treated male patients aged 0 to <6 years (n=25) and aged 6 to 12 years (n=26) with severe hemophilia A (<1% FVIII) (n=51) studied for 6 months

### Dosing
- Dosing regimens were determined by the investigators to meet individual patients' needs
  - 2x/week prophylaxis: 25-50 IU/kg
  - 3x/week or every-other-day (EOD) prophylaxis: 25-50 IU/kg

<table>
<thead>
<tr>
<th>Regimen</th>
<th>0 to &lt;6 years (n=9)</th>
<th>6 to 12 years (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2x/week</td>
<td>36%</td>
<td>50%</td>
</tr>
<tr>
<td>3x/week or EOD</td>
<td>64% (n=16)</td>
<td>50% (n=13)</td>
</tr>
</tbody>
</table>

### Primary endpoint
- Annualized number of total bleeds measured during routine prophylaxis, within 48 hours of previous prophylaxis treatment

### Pharmacokinetics
- After a single 50 IU/kg dose of KOVALTRY®, the demonstrated half-life [mean ± standard deviation (SD)], using the chromogenic assay, in 18 previously treated patients 0 to 12 years of age was:
  - 0 to <6 years (n=7): 12.1 ± 2.7 hours
  - 6 to <12 years (n=10): 12.0 ± 2.1 hours

**SELECTED IMPORTANT SAFETY INFORMATION**

- Hemophilic patients with cardiovascular risk factors or diseases may be at the same risk to develop cardiovascular events as non-hemophilic patients when clotting has been normalized by treatment with Factor VIII.

Please see additional Important Safety Information on following pages. For additional important risk and use information, please see Brief Summary on following pages.
ABR for total bleeds

Primary endpoint: ABR measured within 48 hours

Secondary endpoint: ABR during the 6-month study

89.7% of bleeding episodes resolved with ≤2 infusions of KOVALTRY®

People with hemophilia A may develop inhibitors to rFVIII. People with a history of inhibitors and previously untreated children were excluded from LEOPOLD Kids—Part A.

SELECTED IMPORTANT SAFETY INFORMATION

Catheter-related infections may occur when KOVALTRY® is administered via central venous access devices (CVADs). These infections have not been associated with the product itself.

The most frequently reported adverse reactions in clinical trials (≥3%) were headache, pyrexia, and pruritus.

During the LEOPOLD Kids study, one patient was moved from a 2x/week prophylaxis regimen to a 3x/week regimen.

To an ongoing extension study, a 13-year-old PTP had a titer of 0.8 BU after 550 EDs concurrent with an acute infection and positive IgG anticardiolipin antibodies. His ABR was zero and no change in therapy was required.

*During the LEOPOLD Kids study, one patient was moved from a 2x/week prophylaxis regimen to a 3x/week prophylaxis regimen.

†In an ongoing extension study, a 13-year-old PTP had a titer of 0.6 BU after 550 EDs concurrent with an acute infection and positive IgG anticardiolipin antibodies. His ABR was zero and no change in therapy was required.
**KOVALTRY® TAKING THE NEXT STEP—TOGETHER**

For additional important risk and use information, please see Brief Summary on following pages.

You are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**References:**

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Printed in USA 05/16 PP-675-US-0202

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**SELECTED IMPORTANT SAFETY INFORMATION**

KOVALTRY® is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, to any of the excipients, or to mouse or hamster proteins.

Hypersensitivity reactions, including anaphylaxis, are possible with KOVALTRY®. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea. Discontinue KOVALTRY® if symptoms occur and seek immediate emergency treatment.

---

**Recommended prophylaxis dose**

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Children aged ≤12 years</th>
<th>Adolescents and adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-50 IU/kg</td>
<td>2x/week, 3x/week, or EOD</td>
<td>2x/week or 3x/week</td>
</tr>
</tbody>
</table>

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**Bayer Access Solutions**

- If your patient’s insurance does not cover KOVALTRY®, we may be able to provide KOVALTRY® to your patient at no cost for up to one year while insurance issues are being resolved.*
- **Call 1-800-288-8374** from 8:00 AM-8:00 PM (ET) Monday-Friday to connect with a Case Specialist. Spanish-speaking Case Specialists are also available.

*Some restrictions apply. Please call 1-800-288-8374 to learn more.

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**KOVUS-65121_M2_BR_HCP_Journal_Ad.indd**

Saved at 8-23-2016 1:25 PM by Taylor Raczkowski / Vincent Jeffrey

Images: 65122_hiking_couple_sen_BackCover_S (CMYK; 309 ppi; 97%), KOVALTRY_US_Logo_4C.ai (53.97%); Sub2_KDV_Prime_HR_S (CMYK; 2061 ppi; 14.55%)

Fonts & Colors: Cyan, Magenta, Yellow, Black

**Notes:** HCP Journal Ad | BDI and Rare Diseases Supplement
KOVALTRY [Antihemophilic Factor (Recombinant)]
Lyophilized Powder for Solution for Intravenous Injection – Reconstitution with Vial Adapter
Initial U.S. Approval: 2016

BRIEF SUMMARY
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
KOVALTRY, Antihemophilic Factor (Recombinant), is a recombinant, human DNA sequence derived, full length Factor VIII concentrate indicated for use in adults and children with hemophilia A (congenital Factor VIII deficiency) for:
- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes
KOVALTRY is not indicated for the treatment of von Willebrand disease.

4 CONTRAINDICATIONS
KOVALTRY is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, to any of the excipients, or to mouse or hamster proteins [see Description (11)].

5 WARNINGS AND PRECAUTIONS
5.1 Hypersensitivity Reactions
Hypersensitivity reactions, including anaphylaxis, are possible with KOVALTRY. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea. Discontinue KOVALTRY if symptoms occur and seek immediate emergency treatment.
KOVALTRY may contain trace amounts of mouse and hamster proteins [see Description (11)]. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.

5.2 Neutralizing Antibodies
Neutralizing antibody (inhibitor) formation can occur following administration of KOVALTRY. Previously untreated patients (PUPs) are at greatest risk for inhibitor development with all Factor VIII products [see Adverse Reactions (6.1)]. Carefully monitor patients for the development of Factor VIII inhibitors, using appropriate clinical observations and laboratory tests. If expected plasma Factor VIII activity levels are not attained or if bleeding is not controlled as expected with administered dose, suspect the presence of an inhibitor (neutralizing antibody) [see Warnings and Precautions (5.5)].

5.3 Cardiovascular Risk Factors
Hemophilic patients with cardiovascular risk factors or diseases may be at the same risk to develop cardiovascular events as Hemophilic patients with cardiovascular risk factors or diseases [see Warnings and Precautions (5.5)].

5.4 Catheter-related Infections
Catheter-related infections may be observed when KOVALTRY is administered via central venous access devices (CVADs). These infections have not been associated with the product itself.

5.5 Monitoring Laboratory Tests
- Monitor plasma Factor VIII activity levels using a validated test to confirm that adequate Factor VIII levels have been achieved and maintained [see Dosage and Administration (2.1)].
- Monitor for development of Factor VIII inhibitors. Perform a Bethesda inhibitor assay if expected Factor VIII plasma levels are not attained or if bleeding is not controlled with the expected dose of KOVALTRY. Use Bethesda Units (BU) to report inhibitor titers.

6 ADVERSE REACTIONS
The most frequently reported adverse reactions in clinical trials (≥3%) were headache, pyrexia, and pruritus (see Table 3).

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in clinical practice.
KOVALTRY was evaluated in 193 previously treated patients (PTPs) (inclusive of 51 pediatric patients <12 years of age) with at least three months of exposure to KOVALTRY. The safety analysis was done using a pooled database from three multi-center, prospective, open-label clinical studies. The median time on study for patients ≥12 years of age was 372 days with a median of 159 exposure days (EDs). The median time on study for patients <12 years of age was 182 days with a median of 73 EDs. Subjects who received KOVALTRY for perioperative management (n=5) with treatment period of 2 to 3 weeks and those who received single doses of KOVALTRY for PK studies (n=6) were excluded from safety analysis. Table 3 lists the adverse reactions reported during clinical studies. The frequency, type, and severity of adverse reactions in children are similar to those in adults.

Table 3: Adverse Reactions in PTPs (N=193)

<table>
<thead>
<tr>
<th>Preferred term</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Blood and the Lymphatic System Disorders</td>
<td>2 (1.0%)</td>
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<tr>
<td>Lymphadenopathy</td>
<td>2 (1.0%)</td>
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<tr>
<td>Cardiac Disorders</td>
<td>4 (2.1%)</td>
</tr>
<tr>
<td>Palpitation</td>
<td>3 (1.6%)</td>
</tr>
<tr>
<td>Sinus tachycardia</td>
<td>4 (2.1%)</td>
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<tr>
<td>Gastrointestinal Disorders</td>
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</tr>
<tr>
<td>Abdominal pain</td>
<td>8 (4.1%)</td>
</tr>
<tr>
<td>Abdominal discomfort</td>
<td>2 (1.0%)</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>5 (2.6%)</td>
</tr>
<tr>
<td>General Disorders and Administration Site Conditions</td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>14 (7.3%)</td>
</tr>
<tr>
<td>Chest discomfort</td>
<td>12 (6.2%)</td>
</tr>
<tr>
<td>Injection site reactionsa</td>
<td>5 (2.6%)</td>
</tr>
<tr>
<td>Immune System Disorders</td>
<td></td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td></td>
</tr>
<tr>
<td>Dysgeusia</td>
<td>5 (2.6%)</td>
</tr>
<tr>
<td>Headache</td>
<td>14 (7.3%)</td>
</tr>
<tr>
<td>Psychiatric Disorders</td>
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<tr>
<td>Insomnia</td>
<td>5 (2.6%)</td>
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<tr>
<td>Skinn and Subcutaneous Tissue Disorders</td>
<td>2 (1.0%)</td>
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<tr>
<td>Dermatitis allergic</td>
<td>6 (3.1%)</td>
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<tr>
<td>Pruritus</td>
<td>5 (2.6%)</td>
</tr>
<tr>
<td>Rash*</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>Urticaria</td>
<td></td>
</tr>
<tr>
<td>Vascular disorders</td>
<td></td>
</tr>
<tr>
<td>Hushing</td>
<td>1 (0.5%)</td>
</tr>
</tbody>
</table>

Includes injection site extravasation and hematomas, infusion site pain, pruritus, and swelling
*Includes rash, rash erythematous, and rash pruritic
Immunogenicity
All clinical trial subjects were monitored for neutralizing antibodies (inhibitors) to Factor VIII by the modified Bethesda assay using blood samples obtained prior to the first infusion of KOVALTRY, at defined intervals during the studies and at the completion visit.

Clinical trials (Phases 1 through 3) with KOVALTRY evaluated a total of 204 pediatric and adult patients diagnosed with severe hemophilia A (Factor VIII <1%) with previous exposure to Factor VIII concentrates ≥50 EDs, and no history of inhibitors. In the completed studies, no FPT developed neutralizing antibodies to Factor VIII. In an ongoing extension study, a 13 year old FPT had a titer of 0.6 BU after 550 EDs concurrent with an acute infection and positive IgG anticardiolipin antibodies. The Factor VIII recovery was 2.2 IU/dL per IU/kg, annualized bleeding rate (ABR) was zero, and no change in therapy was required.

In an actively enrolling clinical trial in PUPs, 6 of 14 treated subjects (42.9% with a 95% Confidence Interval of 17.7-71.1%) developed an inhibitor. Of these, 3 subjects (21.4%) had high titer inhibitors, and 3 subjects (21.4%) had transient low titer inhibitors for which no change in therapy was required.

The detection of antibody formation is dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, it may be misleading to compare the incidence of antibodies to KOVALTRY with the incidence of antibodies to other products.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy Risk Summary
There are no data with KOVALTRY use in pregnant women to inform on drug-associated risk. Animal reproduction studies have not been conducted using KOVALTRY. It is not known whether KOVALTRY can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. KOVALTRY should be given to a pregnant woman only if clearly needed. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

8.2 Lactation Risk Summary
There is no information regarding the presence of KOVALTRY in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for KOVALTRY and any potential adverse effects on the breastfed infant from KOVALTRY or from the underlying maternal condition.

8.4 Pediatric Use
Safety and efficacy studies with KOVALTRY have been performed in pediatric PTPs. Body weight adjusted clearance of Factor VIII in children ≤12 years of age is higher than in adults and adolescents. Consider higher or more frequent dosing in children to account for this difference in clearance [see Clinical Pharmacology (12.5)].

8.5 Geriatric Use
Clinical studies with KOVALTRY did not include patients aged 65 and over to determine whether or not they respond differently from younger patients. However, clinical experience with other Factor VIII products has not identified differences between the elderly and younger patients. As with any patient receiving recombinant Factor VIII, dose selection for an elderly patient should be individualized.

17 PATIENT COUNSELING INFORMATION
• Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).
• Hypeasensitivity reactions are possible with KOVALTRY [see Warnings and Precautions (5.1)]. Warn patients of the early signs of hypersensitivity reactions (including tightness of the chest or throat, dizziness, mild hypotension and nausea during infusion) which can progress to anaphylaxis.
• Advise patients to discontinue use of the product if these symptoms occur and seek immediate emergency treatment with resuscitative measures such as the administration of epinephrine and oxygen.
• Inhibitor formation may occur at any time in the treatment of a patient with hemophilia A [see Warnings and Precautions (5.2)]. Advise patients to contact their physician or treatment center for further treatment and/or assessment, if they experience a lack of clinical response to Factor VIII replacement therapy, as this may be a manifestation of an inhibitor.
• Advise patients to discard all equipment, including any unused product, in an appropriate container.
• Advise patients to consult with their healthcare provider prior to travel. Advise patients to bring an adequate supply of KOVALTRY while traveling based on their current regimen of treatment.

Resources at Bayer available to the patient: For Adverse Reaction Reporting, contact Bayer Medical Communications 1-888-84-BAYER (1-888-842-2937) To receive more product information, contact KOVALTRY Customer Service 1-888-606-3780 Bayer Reimbursement HELpline 1-800-288-8374 For more information, visit www.KOVALTRY-us.com Bayer HealthCare LLC Whippany, NJ 07981 USA U.S. License No. 6907500BS

File Info: Client Code: None Client: Bayer/Kogenate
Live: 7" x 10"
Overall Trim: 8" x 10.75" Bled: 9" x 11.75"
# of Colors: 4C +1k Notes: HCP Journal Ad / BDI and Rare Diseases Supplement.
What is IXINITY®?
IXINITY [coagulation factor IX (recombinant)] is a medicine used to replace clotting factor (factor IX) that is missing in adults and children at least 12 years of age with hemophilia B. Hemophilia B is also called congenital factor IX deficiency or Christmas disease. Hemophilia B is an inherited bleeding disorder that prevents clotting. Your healthcare provider may give you IXINITY to control and prevent bleeding episodes or when you have surgery.

IXINITY is not indicated for induction of immune tolerance in patients with Hemophilia B.

IMPORTANT SAFETY INFORMATION FOR IXINITY®

• You should not use IXINITY if you are allergic to hamsters or any ingredients in IXINITY.
• You should tell your healthcare provider if you have or have had medical problems, take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements, or herbal remedies, have any allergies, including allergies to hamsters, are nursing, are pregnant or planning to become pregnant, or have been told that you have inhibitors to factor IX.
• You can experience an allergic reaction to IXINITY. Contact your healthcare provider or get emergency treatment right away if you develop a rash or hives, itching, tightness of the throat, chest pain, or tightness, difficulty breathing, lightheadedness, dizziness, nausea, or fainting.
• Your body may form inhibitors to IXINITY. An inhibitor is part of the body’s defense system. If you develop inhibitors, it may prevent IXINITY from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for development of inhibitors to IXINITY.

• If you have risk factors for developing blood clots, the use of IXINITY may increase the risk of abnormal blood clots.
• Call your healthcare provider right away about any side effects that bother you or do not go away, or if your bleeding does not stop after taking IXINITY.
• The most common side effect that was reported with IXINITY during clinical trials was headache.
• These are not all the side effects possible with IXINITY. You can ask your healthcare provider for information that is written for healthcare professionals.

You are encouraged to report side effects of prescription drugs to the Food and Drug Administration. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying brief summary of Prescribing Information on next page.

Aptevo BioTherapeutics LLC, Berwyn, PA 19312
IXINITY [coagulation factor IX (recombinant)], and any and all Aptevo BioTherapeutics LLC brand, product, service and feature names, logos, and slogans are trademarks or registered trademarks of Aptevo BioTherapeutics LLC in the United States and/or other countries.

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IXINITY® (coagulation factor IX (recombinant))

Brief Summary for the Patient
See package insert for full Prescribing Information. This product’s label may have been updated. For further product information and current package insert, please visit www.IXINITY.com.

Please read this Patient Information carefully before using IXINITY. This brief summary does not take the place of talking with your healthcare provider, and it does not include all of the important information about IXINITY.

What is IXINITY?
IXINITY is a medicine used to replace clotting factor (factor IX) that is missing in people with hemophilia B. Hemophilia B is also called congenital factor IX deficiency or Christmas disease. Hemophilia B is an inherited bleeding disorder that prevents clotting. Your healthcare provider may give you IXINITY when you have surgery.

IXINITY is not indicated for induction of immune tolerance in patients with hemophilia B.

Who should not use IXINITY?
You should not use IXINITY if you:
•  Are allergic to hamsters
•  Are allergic to any ingredients in IXINITY

Tell your healthcare provider if you are pregnant or breastfeeding because IXINITY may not be right for you.

What should I tell my healthcare provider before using IXINITY?
You should tell your healthcare provider if you:
•  Have or have had any medical problems
•  Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements, or herbal remedies
•  Have any allergies, including allergies to hamsters
•  Are breastfeeding. It is not known if IXINITY passes into your milk and if it can harm your baby
•  Are pregnant or planning to become pregnant. It is not known if IXINITY may harm your baby
•  Have been told that you have inhibitors to factor IX (because IXINITY may not work for you)

How should I infuse IXINITY?
IXINITY is given directly into the bloodstream. IXINITY should be administered as ordered by your healthcare provider. You should be trained on how to do infusions by your healthcare provider or hemophilia treatment center. Many people with hemophilia B learn to infuse their IXINITY by themselves or with the help of a family member.

See the step-by-step instructions for infusing in the complete patient labeling.
Your healthcare provider will tell you how much IXINITY to use based on your weight, the severity of your hemophilia B, and where you are bleeding. You may have to have blood tests done after getting IXINITY to be sure that your blood level of factor IX is high enough to stop the bleeding. Call your healthcare provider right away if your bleeding does not stop after taking IXINITY.

What are the possible side effects of IXINITY?
Allergic reactions may occur with IXINITY. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms:
•  Rash
•  Hives
•  Itching
•  Tightness of the throat
•  Chest pain or tightness
•  Difficulty breathing

- Lightheadedness
- Dizziness
- Nausea
- Fainting

Tell your healthcare provider about any side effect that bothers you or does not go away. The most common side effect of IXINITY in clinical trials was headache. These are not all of the possible side effects of IXINITY. You can ask your healthcare provider for information that is written for healthcare professionals.

Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store IXINITY?
250 IU strength only; store at 2 to 8°C (36 to 46°F). Do not freeze.
500, 1000, 1500, 2000 and 3000 IU strengths; store at 2 to 25°C (36 to 77°F). Do not freeze.
Do not use IXINITY after the expiration date printed on the label. Throw away any unused IXINITY and diluents after it reaches this date.
Reconstituted product (after mixing dry product with Sterile Water for Injection) must be used within 3 hours and cannot be stored or refrigerated. Discard any IXINITY left in the vial at the end of your infusion.
After reconstitution of the lyophilized powder, all dosage strengths should yield a clear, colorless solution without visible particles. Discard if visible particulate matter or discoloration is observed.

What else should I know about IXINITY?
Your body may form inhibitors to factor IX. An inhibitor is part of the body’s immune system. If you form inhibitors, it may stop IXINITY from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests to check for the development of inhibitors to factor IX. Consult your doctor promptly if bleeding is not controlled with IXINITY as expected.
Medicines are sometimes prescribed for purposes other than those listed here. Do not use IXINITY for a condition for which it is not prescribed. Do not share IXINITY with other people, even if they have the same symptoms as you.
Always check the actual dosage strength printed on the label to make sure you are using the strength prescribed by your healthcare provider.

Manufactured by:
Aptevo BioTherapeutics LLC
Berwyn PA, 19312
U.S. License No. 2054

Part No: 1000973_1
CM-FIX-0078
Table of Contents
Q4 2016 • Fall

Access our portfolio of products anytime, anywhere.

Albumin 22
- Albumin 5%
- Albumin 25%

I.G. Products 22
- IVIG
- SCIG
- Hyper Immune Globulin
- C1-Esterase inhibitor

Coagulation 25
- Coagulation Factor VIII
- Coagulation Factor VIII / vWF Complex Concentrate
- Deamnpressin Acetate
- Coagulation Factor IX
- Coagulation Factor X
- Coagulation Factor XII
- Anti-Inhibitor Complex
- Prothrombin Complex Concentrate
- Fibrinogen Concentrate

Antithrombin 29
- Antithrombin

Vaccines 30
- Rabies
- Influenza Virus (FLU)
- Human Papillomavirus (HPV)
- Pneumococcal
- Tetanus, Diphtheria & Pertussis

Oncology Products 30

Supportive Care 33

Oral Therapies 34

I.V. Antibiotics 34
- I.V. Antibiotics

Other 34
- Infusion Pumps, SubQ Needles & I.V. Tubing

bdipharma.com 800.948.9834
### Albumin 5%

<table>
<thead>
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<td>Grifols</td>
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<td>Buminate 250mL</td>
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### Intravenous Immune Globulin - Lyophilized

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### Intravenous Immune Globulin - 5% Liquid

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<td>00944-2700-07</td>
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<td>Baxalta</td>
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Call one of our representatives today at 1-800-948-9834 or visit www.bdipharma.com
### Subcutaneous Immune Globulin - 10% Liquid

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### Subcutaneous Immune Globulin - 20% Liquid

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<td>44206-0451-01</td>
<td>Hizentra® 5mL 1 gram vial</td>
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<td>44206-0452-02</td>
<td>Hizentra® 10mL 2 gram vial</td>
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<td>44206-0454-04</td>
<td>Hizentra® 20mL 4 gram vial</td>
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### Hyper Immune Globulin - Rho(D)

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<td>HyperRHO® S/D Full Dose syringe</td>
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<td>13533-0631-10</td>
<td>HyperRHO® S/D Full Dose syringe (10-pack)</td>
<td>Grifols</td>
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<td>13533-0661-06</td>
<td>HyperRHO® S/D Mini-Dose 10 PFS</td>
<td>Grifols</td>
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<td>44206-0300-01</td>
<td>Rhophylac® PFS</td>
<td>CSL Behring</td>
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<td>RhogAM® Ultra-Filtered PLUS 1 prefilled single dose syringe</td>
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### Hyper Immune Globulin - Intramuscular

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<td>VARIZIG® 3mL vial</td>
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### Hyper Immune Globulin - Hepatitis B

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### Hyper Immune Globulin - Rabies

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<td>49281-0190-20</td>
<td>IMOGAM® Rabies-HT 2mL vial</td>
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### Hyper Immune Globulin - Tetanus

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### Hyper Immune Globulin - Cytomegalovirus

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### C1-Esterase Inhibitor

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<td>63833-0825-02</td>
<td>Berinert® 500 unit vial</td>
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### Coagulation Factor VIII - Plasma Derived

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<td>68516-4602-01</td>
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<td>68516-4609-02</td>
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<td>HEMOFIL M NF 250 unit vial w/ 10mL diluent</td>
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Call one of our representatives today at 1-800-948-9834 or visit www.bdipharma.com
## Coagulation Factor VIII - Plasma Derived (cont)

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<td>wilate® vWF / FVIII Complex 500 iu vWF:Rco and 500 iu FVIII in 5mL</td>
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## Coagulation Factor VIII - Recombinant

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<td>ELOCTATE™ 750 iu vial</td>
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<td>ELOCTATE™ 1000 iu vial</td>
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<td>64406-0805-01</td>
<td>ELOCTATE™ 1500 iu vial</td>
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<td>64406-0806-01</td>
<td>ELOCTATE™ 2000 iu vial</td>
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<td>64406-0807-01</td>
<td>ELOCTATE™ 3000 iu vial</td>
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<td>00053-8131-02</td>
<td>Helixate® FS 250 unit vial w/ 2.5mL diluent</td>
<td>CSL Behring</td>
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<tr>
<td>00053-8132-02</td>
<td>Helixate® FS 500 unit vial w/ 2.5mL diluent</td>
<td>CSL Behring</td>
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<td>00053-8133-02</td>
<td>Helixate® FS 1000 unit vial w/ 2.5mL diluent</td>
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<tr>
<td>00053-8134-02</td>
<td>Helixate® FS 2000 unit vial w/ 5mL diluent</td>
<td>CSL Behring</td>
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<tr>
<td>00026-3792-20</td>
<td>Kogenate® FS Bio-Set 250 unit vial w/ 2.5mL diluent</td>
<td>Bayer</td>
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<tr>
<td>00026-3793-30</td>
<td>Kogenate® FS Bio-Set 500 unit vial w/ 2.5mL diluent</td>
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<td>00026-3795-50</td>
<td>Kogenate® FS Bio-Set 1000 unit vial w/ 2.5mL diluent</td>
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<tr>
<td>00026-3796-60</td>
<td>Kogenate® FS Bio-Set 2000 unit vial w/ 5mL diluent</td>
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<td>00026-3797-70</td>
<td>Kogenate® FS Bio-Set 3000 unit vial w/ 5mL diluent</td>
<td>Bayer</td>
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<tr>
<td>00026-3782-25</td>
<td>Kogenate® FS with Vial Adaptor 250 unit vial w/ 2.5mL diluent</td>
<td>Bayer</td>
</tr>
<tr>
<td>00026-3783-35</td>
<td>Kogenate® FS with Vial Adaptor 500 unit vial w/ 2.5mL diluent</td>
<td>Bayer</td>
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<tr>
<td>00026-3785-55</td>
<td>Kogenate® FS with Vial Adaptor 1000 unit vial w/ 2.5mL diluent</td>
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<tr>
<td>00026-3786-65</td>
<td>Kogenate® FS with Vial Adaptor 2000 unit vial w/ 5mL diluent</td>
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<tr>
<td>00026-3787-75</td>
<td>Kogenate® FS with Vial Adaptor 3000 unit vial w/ 5mL diluent</td>
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## Coagulation Factor VIII - Recombinant (cont)

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<th>Product</th>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>00026-3821-25</td>
<td>KOVALTRY® 250 unit vial w/2.5mL diluent</td>
<td>Bayer</td>
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<tr>
<td>00026-3822-25</td>
<td>KOVALTRY® 500 unit vial w/2.5mL diluent</td>
<td>Bayer</td>
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<td>00026-3824-25</td>
<td>KOVALTRY® 1000 unit vial w/2.5mL diluent</td>
<td>Bayer</td>
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<tr>
<td>00026-3826-50</td>
<td>KOVALTRY® 2000 unit vial w/5mL diluent</td>
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<tr>
<td>00026-3828-50</td>
<td>KOVALTRY® 3000 unit vial w/5mL diluent</td>
<td>Bayer</td>
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<td>00169-7825-01</td>
<td>Novoeight® 250 unit vial w/ 4mL diluent</td>
<td>NovoNordisk</td>
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<td>00169-7850-01</td>
<td>Novoeight® 500 unit vial w/ 4mL diluent</td>
<td>NovoNordisk</td>
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<tr>
<td>00169-7810-01</td>
<td>Novoeight® 1000 unit vial w/ 4mL diluent</td>
<td>NovoNordisk</td>
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<td>00169-7815-01</td>
<td>Novoeight® 1500 unit vial w/ 4mL diluent</td>
<td>NovoNordisk</td>
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<td>00169-7820-01</td>
<td>Novoeight® 2000 unit vial w/ 4mL diluent</td>
<td>NovoNordisk</td>
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<td>00169-7830-01</td>
<td>Novoeight® 3000 unit vial w/ 4mL diluent</td>
<td>NovoNordisk</td>
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<tr>
<td>68982-0139-01</td>
<td>NUWIQ® 250 unit vial w/ 2.5mL diluent</td>
<td>Octapharma</td>
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<td>68982-0141-01</td>
<td>NUWIQ® 500 unit vial w/ 2.5mL diluent</td>
<td>Octapharma</td>
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<tr>
<td>68982-0143-01</td>
<td>NUWIQ® 1000 unit vial w/ 2.5mL diluent</td>
<td>Octapharma</td>
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<tr>
<td>68982-0145-01</td>
<td>NUWIQ® 2000 unit vial w/ 2.5mL diluent</td>
<td>Octapharma</td>
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<tr>
<td>00944-2841-10</td>
<td>Recombinate 220-400 unit vial w/ 5mL diluent</td>
<td>Baxalta</td>
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<td>00944-2842-10</td>
<td>Recombinate 401-800 unit vial w/ 5mL diluent</td>
<td>Baxalta</td>
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<tr>
<td>00944-2843-10</td>
<td>Recombinate 801-1240 unit vial w/ 5mL diluent</td>
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<td>Recombinate 1241-1800 unit vial w/ 5mL diluent</td>
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<td>00944-2845-10</td>
<td>Recombinate 1801-2400 unit vial w/ 5mL diluent</td>
<td>Baxalta</td>
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<tr>
<td>58394-0012-01</td>
<td>XYNTHA® 250 unit vial w/ 4mL diluent</td>
<td>Pfizer</td>
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<td>XYNTHA® 500 unit vial w/ 4mL diluent</td>
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<td>58394-0015-01</td>
<td>XYNTHA® 2000 unit vial w/ 4mL diluent</td>
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<tr>
<td>58394-0022-03</td>
<td>XYNTHA® Solofuse® 250 unit w/ 4mL diluent</td>
<td>Pfizer</td>
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<td>58394-0023-03</td>
<td>XYNTHA® Solofuse® 500 unit w/ 4mL diluent</td>
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<tr>
<td>58394-0024-03</td>
<td>XYNTHA® Solofuse® 1000 unit w/ 4mL diluent</td>
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<td>58394-0025-03</td>
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<tr>
<td>58394-0016-03</td>
<td>XYNTHA® Solofuse® 3000 unit w/ 4mL diluent</td>
<td>Pfizer</td>
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## Coagulation Factor VIII / von Willebrand Complex Concentrate

<table>
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<tr>
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<th>Product</th>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>68516-4601-01</td>
<td>Alphanate® AHF/VWF complex 250iu FVIII / 5mL vial (call for RCo)</td>
<td>Grifols</td>
</tr>
<tr>
<td>68516-4602-01</td>
<td>Alphanate® AHF/VWF complex 500iu FVIII / 5mL vial (call for RCo)</td>
<td>Grifols</td>
</tr>
<tr>
<td>68516-4603-02</td>
<td>Alphanate® AHF/VWF complex 1000iu FVIII / 10mL vial (call for RCo)</td>
<td>Grifols</td>
</tr>
<tr>
<td>68516-4604-02</td>
<td>Alphanate® AHF/VWF complex 1500iu FVIII / 10mL vial (call for RCo)</td>
<td>Grifols</td>
</tr>
<tr>
<td>68516-4609-02</td>
<td>Alphanate® AHF/VWF complex 2000iu FVIII / 10mL vial (call for RCo)</td>
<td>Grifols</td>
</tr>
<tr>
<td>63833-0615-02</td>
<td>Humate-P® AHF/VWF complex 500rcu vial (call for iu)</td>
<td>CSL Behring</td>
</tr>
<tr>
<td>63833-0616-02</td>
<td>Humate-P® AHF/VWF complex 1000rcu vial (call for iu)</td>
<td>CSL Behring</td>
</tr>
<tr>
<td>63833-0617-02</td>
<td>Humate-P® AHF/VWF complex 2500rcu vial (call for iu)</td>
<td>CSL Behring</td>
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<tr>
<td>68982-0182-01</td>
<td>wilate® vWF / FVIII Complex 500iu vWF:Rco and 500iu FVIII in 5mL</td>
<td>Octapharma</td>
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<tr>
<td>68982-0182-02</td>
<td>wilate® vWF / FVIII Complex 1000iu vWF:Rco and 1000iu FVIII in 5mL</td>
<td>Octapharma</td>
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</table>

Call one of our representatives today at 1-800-948-9834 or visit www.bdipharma.com
### Desmopressin Acetate

<table>
<thead>
<tr>
<th>NDC</th>
<th>Product</th>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>00053-6871-00</td>
<td>Stimate® Nasal Spray 1.5 mg/mL</td>
<td>CSL Behring</td>
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### Coagulation Factor IX - Plasma Derived

<table>
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<tr>
<th>NDC</th>
<th>Product</th>
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<tbody>
<tr>
<td>68516-3601-02</td>
<td>AlphaNine® S/D 500 unit vial w/ 10mL diluent</td>
<td>Grifols</td>
</tr>
<tr>
<td>68516-3602-02</td>
<td>AlphaNine® S/D 1000 unit vial w/ 10mL diluent</td>
<td>Grifols</td>
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<tr>
<td>68516-3603-02</td>
<td>AlphaNine® S/D 1500 unit vial w/ 10mL diluent</td>
<td>Grifols</td>
</tr>
<tr>
<td>64193-0445-02</td>
<td>Bebulin VH (call for range of units per vial) w/ 20mL diluent</td>
<td>Baxalta</td>
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<tr>
<td>00053-6232-02</td>
<td>Mononine® 500 unit vial w/ 5mL diluent</td>
<td>CSL Behring</td>
</tr>
<tr>
<td>00053-6233-02</td>
<td>Mononine® 1000 unit vial w/ 10mL diluent</td>
<td>CSL Behring</td>
</tr>
<tr>
<td>68516-3201-01</td>
<td>Profilnine® 500 unit vial</td>
<td>Grifols</td>
</tr>
<tr>
<td>68516-3202-02</td>
<td>Profilnine® 1000 unit vial</td>
<td>Grifols</td>
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<tr>
<td>68516-3203-02</td>
<td>Profilnine® 1500 unit vial</td>
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### Coagulation Factor IX - Recombinant

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<tr>
<td>58394-0633-03</td>
<td>BeneFIX® RT 250 unit vial</td>
<td>Pfizer</td>
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<tr>
<td>58394-0634-03</td>
<td>BeneFIX® RT 500 unit vial</td>
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<td>58394-0635-03</td>
<td>BeneFIX® RT 1000 unit vial</td>
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<tr>
<td>58394-0636-03</td>
<td>BeneFIX® RT 2000 unit vial</td>
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<tr>
<td>58394-0637-03</td>
<td>BeneFIX® RT 3000 unit vial</td>
<td>Pfizer</td>
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<tr>
<td>69911-0864-02</td>
<td>IDELVION® 250 unit vial w/ 2.5mL diluent</td>
<td>CSL Behring</td>
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<tr>
<td>69911-0865-02</td>
<td>IDELVION® 500 unit vial w/ 2.5mL diluent</td>
<td>CSL Behring</td>
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<td>69911-0866-02</td>
<td>IDELVION® 1000 unit vial w/ 2.5mL diluent</td>
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<td>69911-0867-02</td>
<td>IDELVION® 2000 unit vial w/ 5mL diluent</td>
<td>CSL Behring</td>
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<tr>
<td>00944-3026-02</td>
<td>RIXUBIS 250 unit vial</td>
<td>Baxalta</td>
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<tr>
<td>00944-3028-02</td>
<td>RIXUBIS 500 unit vial</td>
<td>Baxalta</td>
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<td>00944-3030-02</td>
<td>RIXUBIS 1000 unit vial</td>
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<tr>
<td>00944-3032-02</td>
<td>RIXUBIS 2000 unit vial</td>
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<tr>
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<td>RIXUBIS 3000 unit vial</td>
<td>Baxalta</td>
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<tr>
<td>64406-0911-01</td>
<td>ALPROLIX™ 500 unit vial</td>
<td>Biogen</td>
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<td>64406-0922-01</td>
<td>ALPROLIX™ 1000 unit vial</td>
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<tr>
<td>64406-0933-01</td>
<td>ALPROLIX™ 2000 unit vial</td>
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<tr>
<td>64406-0944-01</td>
<td>ALPROLIX™ 3000 unit vial</td>
<td>Biogen</td>
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<tr>
<td>53270-0270-05</td>
<td>IXINITY® 500 unit vial</td>
<td>Aptevo</td>
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<td>53270-0271-05</td>
<td>IXINITY® 1000 unit vial</td>
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<tr>
<td>53270-0272-05</td>
<td>IXINITY® 1500 unit vial</td>
<td>Aptevo</td>
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<td>53270-0271-06</td>
<td>IXINITY® 2000 Multi-kit (2 vials of 1000 IU)</td>
<td>Aptevo</td>
</tr>
<tr>
<td>53270-0272-06</td>
<td>IXINITY® 3000 Multi-kit (2 vials of 1500 IU)</td>
<td>Aptevo</td>
</tr>
</tbody>
</table>

Call one of our representatives today at 1-800-948-9834 or visit www.bdipharma.com
### Coagulation Factor X

<table>
<thead>
<tr>
<th>NDC</th>
<th>Product</th>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>64208-7752-01</td>
<td>COAGADEX 250 unit vial</td>
<td>BPL</td>
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<tr>
<td>64208-7753-01</td>
<td>COAGADEX 500 unit vial</td>
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### Coagulation Factor XIII

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<th>NDC</th>
<th>Product</th>
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<tbody>
<tr>
<td>63833-0518-02</td>
<td>Corifact® (call for range of units per vial) w/ 20 mL diluent</td>
<td>CSL Behring</td>
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### Coagulation Factor VIIa

<table>
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<th>NDC</th>
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<tbody>
<tr>
<td>00169-7201-01</td>
<td>NovoSeven® RT with MixPro™ 1 mg per vial (1000 micrograms/vial)</td>
<td>NovoNordisk</td>
</tr>
<tr>
<td>00169-7202-01</td>
<td>NovoSeven® RT with MixPro™ 2 mg per vial (2000 micrograms/vial)</td>
<td>NovoNordisk</td>
</tr>
<tr>
<td>00169-7205-01</td>
<td>NovoSeven® RT with MixPro™ 5 mg per vial (5000 micrograms/vial)</td>
<td>NovoNordisk</td>
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<tr>
<td>00169-7208-01</td>
<td>NovoSeven® RT with MixPro™ 8 mg per vial (8000 micrograms/vial)</td>
<td>NovoNordisk</td>
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### Anti-Inhibitor Complex

<table>
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<tbody>
<tr>
<td>64193-0423-02</td>
<td>Feiba NF 500 Units per vial</td>
<td>Baxalta</td>
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<tr>
<td>64193-0424-02</td>
<td>Feiba NF 1000 Units per vial</td>
<td>Baxalta</td>
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<tr>
<td>64193-0425-02</td>
<td>Feiba NF 2500 Units per vial</td>
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### Prothrombin Complex Concentrate

<table>
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<th>Product</th>
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<tbody>
<tr>
<td>63833-0386-02</td>
<td>Kcentra™ 500 unit kit</td>
<td>CSL Behring</td>
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<tr>
<td>63833-0387-02</td>
<td>Kcentra™ 1000 unit kit</td>
<td>CSL Behring</td>
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<tr>
<td>68516-3201-01</td>
<td>Profilnine® S/D 500 unit vial</td>
<td>Grifols</td>
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<tr>
<td>68516-3202-02</td>
<td>Profilnine® S/D 1000 unit vial</td>
<td>Grifols</td>
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<tr>
<td>68516-3203-02</td>
<td>Profilnine® S/D 1500 unit vial</td>
<td>Grifols</td>
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<tr>
<td>64193-0445-02</td>
<td>Bebulin VH (call for range of units per vial) w/ 20mL diluent</td>
<td>Baxalta</td>
</tr>
<tr>
<td>00169-7201-01</td>
<td>NovoSeven® RT with MixPro™ 1 mg per vial (1000 micrograms/vial)</td>
<td>NovoNordisk</td>
</tr>
<tr>
<td>00169-7202-01</td>
<td>NovoSeven® RT with MixPro™ 2 mg per vial (2000 micrograms/vial)</td>
<td>NovoNordisk</td>
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<tr>
<td>00169-7205-01</td>
<td>NovoSeven® RT with MixPro™ 5 mg per vial (5000 micrograms/vial)</td>
<td>NovoNordisk</td>
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<tr>
<td>00169-7208-01</td>
<td>NovoSeven® RT with MixPro™ 8 mg per vial (8000 micrograms/vial)</td>
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<td>Feiba NF 500 Units per vial</td>
<td>Baxalta</td>
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<tr>
<td>64193-0424-02</td>
<td>Feiba NF 1000 Units per vial</td>
<td>Baxalta</td>
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<tr>
<td>64193-0425-02</td>
<td>Feiba NF 2500 Units per vial</td>
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### Fibrinogen Concentrate

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<th>NDC</th>
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<tbody>
<tr>
<td>63833-0891-51</td>
<td>RiaSTAP™ 1100 mg/vial</td>
<td>CSL Behring</td>
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### Antithrombin

<table>
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<tr>
<th>NDC</th>
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<th>Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>42976-0121-01</td>
<td>ATryn® Antithrombin (Recombinant) for Inj. 525 unit vial</td>
<td>rEVO</td>
</tr>
<tr>
<td>42976-0121-02</td>
<td>ATryn® Antithrombin (Recombinant) for Inj. 1750 unit vial</td>
<td>rEVO</td>
</tr>
<tr>
<td>13533-0603-20</td>
<td>Thrombate III® (Human) 500 unit vial</td>
<td>Grifols</td>
</tr>
</tbody>
</table>

Call one of our representatives today at 1-800-948-9834 or visit www.bdipharma.com
### Vaccines - Rabies

<table>
<thead>
<tr>
<th>NDC</th>
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<tr>
<td>49281-0250-51</td>
<td>IMOVAX® Rabies Vaccine 1mL SDV</td>
<td>Sanofi Pasteur</td>
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### Vaccines - Influenza Virus (FLU)

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<tbody>
<tr>
<td>33332-0015-01</td>
<td>Afluria® 10pk 0.5mL syringes</td>
<td>bioCSL</td>
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<td>33332-0115-10</td>
<td>Afluria® 5mL MDV (10 doses)</td>
<td>bioCSL</td>
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<td>66521-0118-10</td>
<td>Fluvirin® 5mL MDV</td>
<td>Novartis</td>
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<tr>
<td>66521-0118-02</td>
<td>Fluvirin® 0.5mL 10pk PFS</td>
<td>Novartis</td>
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<td>62577-0614-01</td>
<td>FLUCELVAX® 10 single dose 0.5mL syringes</td>
<td>Novartis</td>
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<td>49281-0515-25</td>
<td>Fluzone® Pediatric Dose 0.25mL 10pk PFS</td>
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<tr>
<td>49281-0397-65</td>
<td>Fluzone® HighDose 0.5mL 10pk PFS</td>
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### Vaccines - Human Papillomavirus 9-valent (HPV)

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<tr>
<td>00006-4119-03</td>
<td>Gardasil®9 0.5mL vial 10pk vials</td>
<td>Merck</td>
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<tr>
<td>00006-4121-02</td>
<td>Gardasil®9 0.5mL Pre-filled Luer Lock syringes w/ tip caps (10pk)</td>
<td>Merck</td>
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### Vaccines - Pneumococcal

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<td>00006-4837-03</td>
<td>Pneumovax® 23 - Inj 25 mcg/0.5mL 10 pack</td>
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### Vaccines - Tetanus, Diphtheria & Pertussis

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<td>49281-0400-10</td>
<td>Adacel® (Tdap) 10x1 dose vial</td>
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<td>49281-0400-15</td>
<td>Adacel® Vaccine 5x1 syringes</td>
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### Oncology Products

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<td>43598-0305-62</td>
<td>Azacitidine INJ 100mg vial</td>
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<td>00703-4239-01</td>
<td>Carboplatin 600mg/60mL</td>
<td>Teva</td>
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<td>61703-0339-50</td>
<td>Carboplatin INJ 450mg/45mL</td>
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<td>61703-0339-56</td>
<td>Carboplatin INJ 600mg/60mL</td>
<td>Hospira</td>
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<td>25021-0202-51</td>
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<td>55111-0556-10</td>
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## Oncology Products (cont)

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<td>Accord</td>
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<td>Teva</td>
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<td>Oxaliplatin 5mg/mL, 50mg</td>
<td>Teva</td>
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<tr>
<td>00781-3315-70</td>
<td>Oxaliplatin 50mg/10mL</td>
<td>Sandoz</td>
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<tr>
<td>00781-3317-80</td>
<td>Oxaliplatin 100mg/20mL</td>
<td>Sandoz</td>
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<td>Paclitaxel 3mg/mL - 30mg/5mL</td>
<td>Hospira</td>
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<tr>
<td>00703-4764-01</td>
<td>Paclitaxel INJ 30mg/5mL</td>
<td>Teva</td>
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<tr>
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<td>Mylan</td>
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<td>67457-0449-17</td>
<td>Paclitaxel INJ 100mg/16.7mL</td>
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<td>Mylan</td>
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<td>Paclitaxel INJ 300mg/50mL</td>
<td>Teva</td>
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<tr>
<td>45963-0613-59</td>
<td>Paclitaxel INJ 300mg</td>
<td>Actavis</td>
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<tr>
<td>00008-1179-01</td>
<td>Torisel® 25mg/mL Kit</td>
<td>Pfizer</td>
</tr>
</tbody>
</table>

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### Oncology Products (cont)

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<tr>
<th>NDC</th>
<th>Product</th>
<th>Manufacturer</th>
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<tr>
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<td>Topotecan HCl INJ 4mg</td>
<td>Accord</td>
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<td>25021-0236-04</td>
<td>Topotecan HCl INJ 4mg</td>
<td>Sagent</td>
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<td>67457-0474-04</td>
<td>Topotecan INJ 4mg</td>
<td>Mylan</td>
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<td>45963-0615-56</td>
<td>Topotecan 4mg</td>
<td>Actavis</td>
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<td>00703-4714-01</td>
<td>Topotecan INJ 4mg</td>
<td>Teva</td>
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<td>63020-0049-01</td>
<td>Velcade® 3.5mg</td>
<td>Millennium</td>
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<td>25021-0204-05</td>
<td>Vinorelbine Tartrate INJ 10mg/mL, 5mL</td>
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<td>61703-0341-09</td>
<td>Vinorelbine Tartrate INJ 50mg/5mL</td>
<td>Hospira</td>
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<td>Vinorelbine INJ 50mg/5mL</td>
<td>Mylan</td>
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<tr>
<td>45963-0607-56</td>
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<tr>
<td>67457-0390-54</td>
<td>Zoledronic Acid 4mg/5mL</td>
<td>Mylan</td>
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<tr>
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<td>25021-0830-82</td>
<td>Zoledronic Acid 5mg/100mL</td>
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<td>Zoledronic Acid 4mg/5mL</td>
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### Supportive Care

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<tbody>
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<td>Dexamethasone 10mg/mL</td>
<td>West-Ward</td>
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<tr>
<td>67457-0420-10</td>
<td>Dexamethasone Sodium Phosphate Injection, USP 100mg/10 mL vial</td>
<td>Mylan</td>
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<tr>
<td>00641-0376-25</td>
<td>Diphenhydramine 50mg/mL</td>
<td>West-Ward</td>
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<tr>
<td>67457-0124-10</td>
<td>Diphenhydramine HCl Injection 50mg/mL</td>
<td>Mylan</td>
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<tr>
<td>00006-3941-32</td>
<td>Emend® 150mg/10mL</td>
<td>Merck</td>
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<tr>
<td>64679-0661-02</td>
<td>Granisetron HCl INJ 1mg/mL, 4mL MDV</td>
<td>Wockhardt</td>
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<tr>
<td>25021-0781-04</td>
<td>Granisetron HCl INJ 1mg/mL, 4mL</td>
<td>Sagent</td>
</tr>
<tr>
<td>00143-9745-05</td>
<td>Granisetron INJ 4mg/4mL 5 pack</td>
<td>West-Ward</td>
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<tr>
<td>66758-0035-01</td>
<td>Granisetron INJ 1mg/1mL, 1mL</td>
<td>Sandoz</td>
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<td>66758-0036-01</td>
<td>Granisetron INJ 1mg/1mL, 4mL</td>
<td>Sandoz</td>
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<td>25021-0400-30</td>
<td>Heparin Sodium INJ 1,000 units/mL - 25 x 30mL</td>
<td>Sagent</td>
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<td>00409-2720-03</td>
<td>Heparin Sodium INJ 1,000 units/mL - 25 x 30mL</td>
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<td>67457-0220-05</td>
<td>Isosulfan Blue INJ 1%, 6x5mL Single Use Vials</td>
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<td>Teva</td>
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### Oral Therapies

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### I.V. Antibiotics

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<td>44567-0241-10</td>
<td>Cefepime HCl INJ 2g (10-pack)</td>
<td>WG Critical Care</td>
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<td>00143-9857-25</td>
<td>Ceftriaxone INJ 1g/10mL</td>
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<td>00143-9856-25</td>
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<td>00409-7332-01</td>
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### Snake Antivenom

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### Infusion Pumps, SubQ Needles & IV Tubing

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<tr>
<td>BDI Pharma is an</td>
<td>FREEDOM60® pump - Call BDI Pharma for details.</td>
<td>RMS Medical Products</td>
</tr>
<tr>
<td>Authorized Distributor</td>
<td>FreedomEdge™ pump - Call BDI Pharma for details.</td>
<td>RMS Medical Products</td>
</tr>
<tr>
<td>for the full line of RMS</td>
<td>Subcutaneous Safety Needle Sets - Call BDI Pharma for details.</td>
<td>RMS Medical Products</td>
</tr>
<tr>
<td>Infusion Products</td>
<td>Precision Flow Rate Tubing - Call BDI Pharma for details.</td>
<td>RMS Medical Products</td>
</tr>
<tr>
<td>for the full line of RMS</td>
<td>Starter Kits - Call BDI Pharma for details.</td>
<td>RMS Medical Products</td>
</tr>
</tbody>
</table>

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