Explore KOVALTRY® with Confidence

The only unmodified, full-length rFVIII offering the potential for as few as 2 infusions per week[1]*

***Compared to other rFVIII products**

INDICATION

- 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.

For additional important risk and use information, please see full Prescribing Information.

Kovaltry®

Antihemophilic Factor (Recombinant)

KOVALTRY® Treatment for Adolescents & Adults

LEOPOLD I Clinical Trial: Main Study

Proven efficacy and safety in adolescents and adults with prophylaxis using as few as 2 infusions per week[1]

LEOPOLD I Trial[1,2]	
Study description	Multinational, open-label, prospective trial evaluating pharmacokinetics, efficacy, safety, and perioperative management of bleeding with KOVALTRY Previously treated male patients (PTPs) aged 12 to 65 years with severe hemophilia A (<1% FVIII) (N=73) studied for 1 year
Dosing	Dosing regimens were determined by the investigators to meet individual patients' needs 2x/week prophylaxis: 20-50 IU/kg (n=18) 3x/week prophylaxis: 20-50 IU/kg (n=44)
Primary efficacy endpoint	Annualized bleed rate (ABR) at 12 months (n=62 for efficacy analysis)

LEOPOLD=Long-Term Efficacy Open-Label Program in Severe Hemophilia A Disease

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.

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Kovaltry®
Antihemophilic Factor (Recombinant)

▶ KOVALTRY® Treatment for Adolescents & Adults

LEOPOLD I Clinical Trial: Main Study

ABR by Dosing Regimen[1]

Dosing was determined by investigators 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 experienced[1,2]

1 **Median ABR** (n=18) (IQR=0.0; 8.0)

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

Patients who generally began the study with more bleeds and a higher percentage of target joints were selected for

3x/week prophylaxis and experienced[1,2]

2 **Median ABR** (n=44) (IQR=0.5; 5.0)

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

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

0 **Inhibitors**

in 62 previously treated patients[1]

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

IQR=interquartile range

SELECTED IMPORTANT SAFETY INFORMATION

- Neutralizing antibody (inhibitor) formation has occurred 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.

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LEOPOLD I Clinical Trial: Main Study Pharmacokinetics (PK) Parameters

The PK parameters of KOVALTRY were investigated in 26 previously treated adolescent and adult patients with severe Hemophilia A following administration of 50 IU/kg of KOVALTRY[1]

Chromogenic Substrate Assay[1]		
Parameter [unit]	**12 to 17 yrs (N=5)**	**≥18 yrs (N=21)**
AUC [IU*h/dL]	1572.0 ± 448.0	2103.4 ± 702.8
C_{max} [IU/dL]	132.5 ± 46.3	133.1 ± 20.4
$t_{½}$ [h]	14.4 ± 5.5	14.2 ± 3.5
CL [dL/h/kg]	0.034 ± 0.010	0.027 ± 0.010

Parameter [unit]	**≥12 yrs (N=115)**
Median Incremental Recovery (IU/dL per IU/kg)	2.3 (1.8; 2.6)

RESULTS EXPRESSED AS ARITHMETIC MEAN ± SD

AUC: area under the curve
C_{max}: maximum drug concentration in plasma after single dose
$t_{½}$: terminal half-life
CL: clearance

LEOPOLD=Long-Term Efficacy Open-Label Program in Severe Hemophilia A Disease

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.

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LEOPOLD I Clinical Trial: Main Study Pharmacokinetics (PK) Parameters

One-Stage Clotting Assay[1]		
Parameter [unit]	**12 to 17 yrs (N=5)**	**≥18 yrs (N=21)**
AUC [IU*h/dL]	1013.9 ± 286.8	1601.3 ± 520.0
C_{max} [IU/dL]	91.7 ± 28.7	99.7 ± 14.9
$t_{½}$ [h]	11.7 ± 1.11	14.3 ± 3.7
CL [dL/h/kg]	0.053 ± 0.017	0.035 ± 0.012

Parameter [unit]	**≥12 yrs (N=115)**
Median Incremental Recovery (IU/dL per IU/kg)	2.2 (1.8; 2.4)

RESULTS EXPRESSED AS ARITHMETIC MEAN ± SD

AUC: area under the curve
C_{max}: maximum drug concentration in plasma after single dose
$t_{½}$: terminal half-life
CL: clearance

SELECTED IMPORTANT SAFETY INFORMATION

- Neutralizing antibody (inhibitor) formation has occurred 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.

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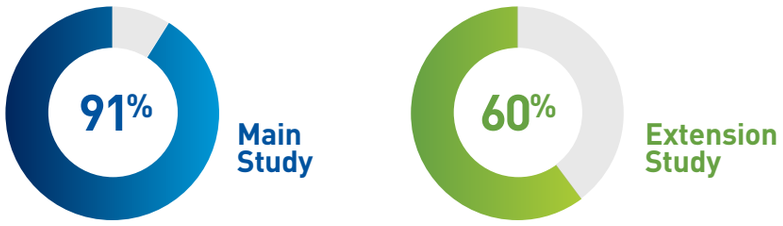
KOVALTRY® Treatment for Adolescents & Adults

LEOPOLD I Clinical Trial: Main and Extension Study

LEOPOLD I Extension Study[1,3]

Extension Study Design	◤ The extension was an optional continuation of the prophylaxis treatment for up to 12 additional months, during which time subjects were treated with KOVALTRY. ◤ The extension study aimed to assess the long-term safety and efficacy profile of treatment with KOVALTRY (up to 2 years of treatment in the main and extension period).* ◤ Patients aged 12 to 17 years (N=10) and aged ≥18 years (N=52) who completed the 1-year study period could be enrolled in the extension to collect additional safety and efficacy data.
Patients Moved to Extension Study	◤ 55 patients: aged 12 to 17 years (n=8) and aged >18 (n=47)*

Median percentage of joint bleeds affecting target joints decreased from main to extension study[3]



Median time to first bleed was prolonged from main to extension study[3]

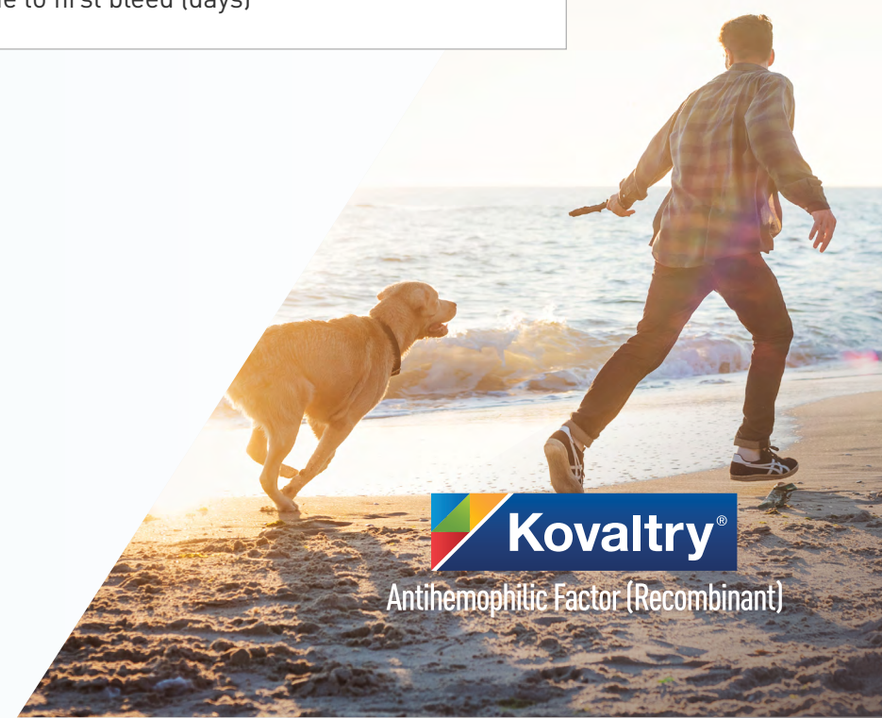
*43 patients completed the extension study

LEOPOLD=Long-Term Efficacy Open-Label Program in Severe Hemophilia A Disease

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.
- 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 (≥5%) were inhibitors in previously untreated patients (PUPs)/ minimally treated patients (MTPs), and pyrexia, headache, and rash.

For additional important risk and use information, please see full Prescribing Information.



KOVALTRY® Treatment for Adolescents & Adults

LEOPOLD I Clinical Trial: Main and Extension Study

During the LEOPOLD I Main Study (N=62) and Extension Study (N=55), KOVALTRY demonstrated safety across patients aged 12 and older[1,3*]

Incidence of drug-related AE/SAEs in the Main Study period[1]

- Drug-related AEs: 6.5%; Drug-related SAEs: 0.0%

Incidence of drug-related AE/SAEs in the Extension Study period[3]

- Drug-related AEs: 5.5%; Drug-related SAEs: 1.8%

In the extension study period, one patient discontinued KOVALTRY due to an SAE[3†]

Most common (≥5%) adverse events were:[1,3]

- Inhibitors in previously untreated patients (PUPs)/minimally treated patients (MTPs),
- Pyrexia, headache and rash

0 During the main and extension studies, no patient developed inhibitor antibodies to FVIII[1,3]

*The extension period starts after the final visit in the main study and ends with final visit in extension study.

†There was 1 SAE, a myocardial infarction, in a patient with known risk factors for cardiovascular events. The investigator considered this event to be treatment related, but not related to the specific study drug. The patient recovered after 2 weeks on remedial drug therapy.

INDICATION

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  - 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.

For additional important risk and use information, please see full Prescribing Information.

Kovaltry®
Antihemophilic Factor (Recombinant)

KOVALTRY® Treatment for Children

LEOPOLD Kids Trial: Main Study

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

LEOPOLD Kids Trial—Part A[1]

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

Regimen	0 to <6 years	6 to <12 years
2x/week	36% (n=9)	50% (n=13)
3x/week or EOD	64% (n=16)	50% (n=13)

Primary endpoint

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

LEOPOLD=Long-Term Efficacy Open-Label Program in Severe Hemophilia A Disease

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.

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LEOPOLD Kids Trial: Main Study

ABR for Total Bleeds[1]

Primary endpoint:
ABR measured within 48 hours[1,4]

0 Median ABR (n=51) (IQR=0.0; 4.0)

Secondary endpoint:
ABR during the 6-month study[1,4]

2 Median ABR (n=51) (IQR=0.0; 6.0)

2x/week prophylaxis

2 Median ABR (n=21)* (range: 0-14.1)

3x/week or EOD prophylaxis

2 Median ABR (n=30)* (range: 0-18.1)

0 Inhibitors
in 51 previously treated patients[1†]

No confirmed cases of neutralizing antibodies (inhibitors) to FVIII occurred.

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[1]

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

†One case of transient low titer inhibitor (0.6 BU/mL (peak titer: 1.0 BU/mL)) occurred in a 13 year old PTP after 549 EDs concurrent with an acute infection and positive IgG anticardiolipin antibodies. The Factor VIII recovery was normal (2.7 IU/dL per IU/kg), annualized bleeding rate (ABR) was zero, and no change in therapy was required.[1]

IQR=interquartile range

SELECTED IMPORTANT SAFETY INFORMATION

- Neutralizing antibody (inhibitor) formation has occurred 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.

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Kovaltry®
Antihemophilic Factor (Recombinant)

▶ KOVALTRY® Treatment for Children

LEOPOLD Kids Trial: Main Study Pharmacokinetic (PK) Parameters

The PK parameters of KOVALTRY were investigated in 20 previously treated patients, 0 to <12 years of age, with severe Hemophilia A following administration of 50 IU/kg of KOVALTRY[1]

Chromogenic Substrate Assay[1,a]			
Parameter [unit]	**0 to <2 yrs (N=4)**	**2 to <6 yrs (N=6)**	**6 to <12 yrs (N=10)[c]**
AUC [IU*h/dL]	1232.5 ± 581.3	1484.8 ± 411.3[b]	1214.5 ± 395.1
C_{max} [IU/dL]	96.1 ± 20.4	83.3 ± 28.7[b]	81.6± 17.8
$t_{½}$ [h]	9.6 ± 3.1	12.2 ± 3.1[b]	12.0 ± 2.1
CL [dL/h/kg]	0.050 ± 0.024	0.034 ± 0.011[b]	0.045 ± 0.016

RESULTS EXPRESSED AS ARITHMETIC MEAN ± SD

AUC: area under the curve
C_{max}: maximum drug concentration in plasma after single dose
$t_{½}$: terminal half-life
CL: clearance

[a] Only Chromogenic Substrate Assay was used for PK parameter assessment in LEOPOLD Kids.
[b] n=5
[c] One subject considered PK outlier was excluded.

LEOPOLD=Long-Term Efficacy Open-Label Program in Severe Hemophilia A Disease

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.
- 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 (≥5%) were inhibitors in previously untreated patients (PUPs)/minimally treated patients (MTPs), and pyrexia, headache, and rash.

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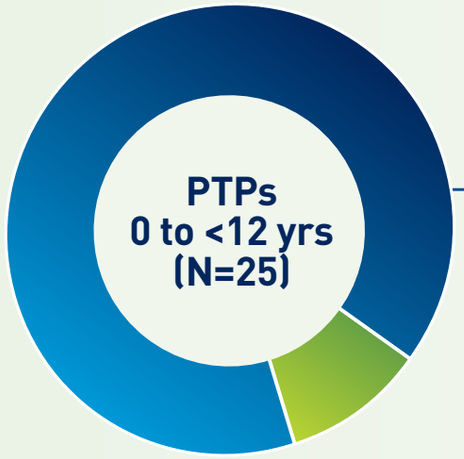
Kovaltry®
Antihemophilic Factor (Recombinant)

▶ KOVALTRY® Treatment for Children

LEOPOLD Kids Trial: Main Study Pharmacokinetic (PK) Parameters

Chromogenic Substrate Assay[1]		
Parameter [unit]	**0 to <6 yrs (N=25)**	**6 to <12 yrs (N=25)**
Median Incremental Recovery (IU/dL per IU/kg)	1.6 (1.3; 1.9)	1.7 (1.4; 2.0)

RESULTS EXPRESSED AS ARITHMETIC MEDIAN (Q1; Q3)



89.7%
of bleeding episodes resolved with ≤2 infusions of KOVALTRY[1]

INDICATION

- 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.

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Kovaltry®
Antihemophilic Factor (Recombinant)

KOVALTRY® Treatment for Children

LEOPOLD Kids Clinical Trial: Main and Extension Study

LEOPOLD Kids Extension Study[5]	
Extension Study Design	◤ The extension was an optional continuation of the prophylaxis treatment for up to 12 additional months, during which time subjects were treated with KOVALTRY. ◤ The extension study aimed to assess long-term safety of KOVALTRY in patients with at least 100 accumulated exposure days across the main and extension studies. ◤ Patients aged 0 to <6 years (n=25) and aged 6 to <12 years (n=26) could roll over after reaching at least 50 exposure days in order to achieve at least 100 cumulative exposure days.
Moved to Extension Study	46 patients*

*45 patients completed the extension study

LEOPOLD=Long-Term Efficacy Open-Label Program in Severe Hemophilia A Disease

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.

For additional important risk and use information, please see full Prescribing Information.

▶ KOVALTRY® Treatment for Children

LEOPOLD Kids Clinical Trial: Main and Extension Study

During the LEOPOLD Kids Main Study (N=51) and Extension Study (N=46), KOVALTRY demonstrated safety across patients aged 0 to <12 years[1,5*]

Incidence of drug-related AE/SAEs in the Main Study period[1]

- Drug-related AEs: 2.0%; Drug-related SAEs: 0.0%

Incidence of drug-related AE/SAEs in the Extension Study period[5]

- Drug-related AEs: 2.2%; Drug-related SAEs: 2.2%

0 Zero patients discontinued KOVALTRY due to AE/SAEs[1,5]

Most common (≥5%) adverse events were:[1,5]

- Inhibitors in previously untreated patients (PUPs)/minimally treated patients (MTPs)
- Pyrexia, headache and rash

0 During the extension study (including measurements at 50-75 exposure days and ≥100 exposure days), no patients developed a new FVIII inhibitor[5]

*The extension period starts after the final visit in the main study and ends with the final visit in extension study.

SELECTED IMPORTANT SAFETY INFORMATION

- Neutralizing antibody (inhibitor) formation has occurred 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.

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Kovaltry®
Antihemophilic Factor (Recombinant)

KOVALTRY® Manufacturing, Reconstitution and Storage

KOVALTRY is manufactured using state-of-the-art techniques[1,6]

25

KOVALTRY has a FVIII **primary protein structure** that has been in use for more than **25 years**[1]

KOVALTRY is an **unmodified, full-length** rFVIII product. Post-translational modifications are similar to those of **natural FVIII**[1]

Human heat shock protein (HSP70), a chaperone protein, was introduced intracellularly to **improve proper folding of the FVIII protein**[1]

Human- and animal-derived raw materials are **not added** in the cell culture, purification, or formulation processes[1]

20-nm filtration step designed to remove potential small viruses[1]

nm=nanometer

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.
- 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.

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Kovaltry®
Antihemophilic Factor (Recombinant)

KOVALTRY® Manufacturing, Reconstitution and Storage

The KOVALTRY needleless reconstitution system contains[1]:

- Vial adapter with built-in 15-micrometer filter
- 2.5 mL or 5.0 mL prefilled diluent syringe
- 25-gauge butterfly needle

Storage at room temperature (up to 77°F) for up to 1 year[1]

Store KOVALTRY at 36°F to 46°F for up to 30 months from the date of manufacture. Do not freeze. Within this period, KOVALTRY may be stored for a period of up to 12 months at temperatures up to 77°F. Record the starting date of room temperature storage clearly on the unopened product carton. Once stored at room temperature, do not return the product to the refrigerator. The product then expires after storage at room temperature for 12 months, or after the expiration date on the product vial, whichever is earlier. Store vials in their original carton and protect them from extreme exposure to light.

KOVALTRY is available in a wide range of vial sizes[1]

- Reconstitution with small diluent volumes

SELECTED IMPORTANT SAFETY INFORMATION

- The most frequently reported adverse reactions in clinical trials (≥5%) were inhibitors in previously untreated patients (PUPs)/minimally treated patients (MTPs), and pyrexia, headache, and rash.

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Kovaltry®
Antihemophilic Factor (Recombinant)

Explore KOVALTRY® with Confidence

The only unmodified, full-length rFVIII offering the potential for as few as 2 infusions per week[1*]

Mean number of prophylaxis infusions per patient[2]

In LEOPOLD I Main and Extension Study:

90 Fewer infusions with 2x/week vs 3x/week prophylaxis during the 2-year study period[2,3]

	Recommended prophylaxis dose	Regimen
Children aged ≤12 years[1]	25-50 IU/kg	2x/week, 3x/week, or EOD
Adolescents and adults[1]	20-40 IU/kg	2x/week or 3x/week

*Compared to other rFVIII products

INDICATION

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- 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.

References: 1. KOVALTRY [prescribing information]. Whippany, NJ: Bayer HealthCare LLC; 2021. **2.** Data on file. Bayer HealthCare Pharmaceuticals, Inc; 2016. **3.** Bayer Data on File, April 2024. LEOPOLD I Extension. BAY 81-8973. 12594 Extension. Clinical Study Report Addendum 1, PH37225. **4.** Ljung R, Kenet G, Mancuso ME, et al. BAY 81-8973 safety and efficacy for prophylaxis and treatment of bleeds in previously treated children with severe hemophilia A: results of the LEOPOLD Kids Trial [published online December 9, 2015]. *Haemophilia*. doi:10.1111/hae.12866. **5.** Bayer Data on File, April 2024. LEOPOLD Kids Extension. BAY 81-8973. 13400 Extension. Clinical Study Report, PH-41325. **6.** Garger S, Wu P, Regan L, et al. BAY 81-8973: a full-length, unmodified, recombinant human factor VIII product created through advanced manufacturing technologies. Poster presented at: European Association for Haemophilia and Allied Disorders 9th Annual Congress; February 2016; Malmö, Sweden.

For additional important risk and use information, please see full Prescribing Information.

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

Kovaltry®
Antihemophilic Factor (Recombinant)