PROFILNINE- factor ix complex
GRIFOLS USA, LLC

Factor IX Complex
Profilnine®

DESCRIPTION

Profilnine®, Factor IX Complex, is a solvent/detergent treated, nanofiltered, sterile, lyophilized concentrate of coagulation factors IX, II, X, and low levels of factor VII. The factor II content is not more than (NMT) 150 units* per 100 factor IX units, the factor X content is NMT 100 units per 100 factor IX units, and the factor VII content is NMT 35 units per 100 factor IX units. Profilnine does not contain heparin and contains no preservatives. Profilnine contains few, if any, activated factors based on results from the non-activated partial thromboplastin time (NAPTT) test[1,2].

Profilnine is intended for intravenous administration only. Each vial is a single-dose container and is labeled with the factor IX potency expressed in International Units.

Profilnine is prepared from pooled human plasma and purified by diethylaminoethyl (DEAE) cellulose adsorption. The risk of transmission of infective agents by Profilnine has been substantially reduced by donor selection procedures and virus screening of individual donations and plasma pools by serological and nucleic acid testing. In addition, virus elimination steps such as nanofiltration[3] and solvent/detergent (tri-n-butyl phosphate) treatment[4] have been incorporated into the Profilnine manufacturing process. Additional removal of some viruses occurs during the DEAE cellulose product purification step.

The ability of the manufacturing process to eliminate virus from Profilnine was evaluated in the laboratory by intentionally adding virus to product just prior to the elimination step and monitoring virus removal. Table 1 shows the amounts of virus that can be removed by solvent/detergent treatment, nanofiltration, and purification by DEAE chromatography when vesicular stomatitis virus (VSV), human immunodeficiency virus-1 and 2 (HIV-1, HIV-2), parvovirus, West Nile virus (WNV), bovine viral diarrhea virus (BVDV), hepatitis A virus (HAV), and pseudorabies virus (PRV) were evaluated in these virus spiking studies. The results indicate that the solvent/detergent treatment step inactivates enveloped viruses and the nanofiltration step removes both enveloped and non-enveloped viruses.

* Unit refers to International Unit in the labeling of Profilnine.

Table 1: Virus Reduction

Virus	Virus Type	Model For:	Virus Reduction ($\log_{10}$) Process Step		
			1st DEAE Chromatography	Solvent-Detergent	Nanofiltration
Sindbis	Env	Hepatitis C	1.4	≥ 5.3	NT
	Env	Robust enveloped			

VSV	Env	Robust enveloped viruses	NT	≥ 4.9	NT
HIV-1	Env	HIV-1	NT	≥ 12.2	≥ 6.2
HIV-2	Env	HIV-2	NT	≥ 6.0	NT
WNV	Env	WNV	NT	NT	≥ 6.6
BVDV	Env	Hepatitis C	NT	NT	≥ 4.9
Parvo*	Non-Env	Parvovirus B19	NT	NT	≥ 6.1
HAV	Non-Env	HAV	NT	NT	≥ 5.8
PRV	Env	Hepatitis B	NT	NT	≥ 5.3

* Porcine, NT=Not tested, Env=Enveloped

CLINICAL PHARMACOLOGY

Profilnine is a mixture of the vitamin K-dependent clotting factors IX, II, X, and low levels of VII. The administration of Profilnine temporarily increases the plasma levels of factor IX, thus enabling a temporary correction of the factor deficiency.

A clinical study that evaluated twelve subjects with hemophilia B indicated that, following administration of Profilnine, the factor IX in vivo half-life was 24.68 ± 8.29 hours and recovery was 1.15 ± 0.16 units/dL per unit infused per kg body weight.

Administration of Factor IX Complex can result in higher than normal levels of factor II due to the significantly longer half-life of factor II[5].

INDICATIONS AND USAGE

Profilnine, Factor IX Complex, is indicated for the prevention and control of bleeding in patients with factor IX deficiency (hemophilia B).

Profilnine contains non-therapeutic levels of factor VII and is not indicated for use in the treatment of factor VII deficiency.

CONTRAINDICATIONS

None known.

WARNINGS

Transmissible Infectious Agents

Because Profilnine is made from human blood, it 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.

Inhibitors

Patients can develop neutralizing antibodies (inhibitors) after treatment with Profilnine. Monitor patients for inhibitors, which should be quantified in Bethesda Units (BU) using appropriate laboratory testing.

Hypersensitivity

Hypersensitivity, including anaphylaxis, has been reported. Inform patients of the early symptoms and signs of hypersensitivity reaction, including hives, generalized urticaria, angioedema, chest tightness, dyspnea, wheezing, faintness, hypotension, tachycardia, and anaphylaxis.

Thrombosis

The use of factor IX complex concentrates has been associated with the development of thromboembolic complications. Patients at increased risk for thrombosis include those undergoing surgery, post surgery, with known liver disease, and with signs of fibrinolysis**,** thrombosis, or disseminated intravascular coagulation (DIC)[5]. When administering Profilnine to these high-risk patients, monitor for early signs of consumptive coagulopathy with appropriate laboratory testing. Only administer Profilnine to patients when the benefits outweigh the risks.

PRECAUTIONS

Vasomotor reactions may result from overly rapid administration. Do not exceed the recommended infusion rate of 10 mL/min.

Information for Patients

Advise patients to report to their physician any decrease in effectiveness of Factor IX treatment, as this can indicate development of inhibitors.

Hypersensitivity, including anaphylaxis, has been reported for factor IX complex concentrate products. Inform patients of the early symptoms and signs of hypersensitivity reaction, including hives, rash, swelling, chest tightness, shortness of breath, wheezing, faintness, decrease in blood pressure, and rapid heartbeat. Advise patients to discontinue use of the product and contact their physician and/or seek immediate emergency care if these symptoms occur.

Pregnancy

Animal reproduction studies have not been conducted with Profilnine. It is also not known whether Profilnine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Only give Profilnine to a pregnant woman if clearly indicated.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Natural Rubber Latex Sensitivity

Certain components used in the packaging of this product contain natural rubber latex. In patients with sensitivity to natural rubber latex, use Profilnine only if needed.

ADVERSE REACTIONS

Adverse reactions with Profilnine may include headache, fever, chills, flushing, nausea,

vomiting, tingling, lethargy, urticaria, and manifestations of allergic reactions.

The following adverse reactions have been identified during post-approval use of Profilnine: hypersensitivity reactions including shortness of breath, diaphoresis, and hypotension, as well as thrombosis including pulmonary embolism and deep vein thrombosis, disseminated intravascular coagulation, and inhibitor development. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

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

DOSAGE AND ADMINISTRATION

Dose

Each vial of Profilnine is labeled with total units expressed as International Units (IU). According to the WHO International Standard, one unit approximates the activity in one mL of normal plasma.

A 1% increase in factor IX (0.01 units) per unit administered per kg body weight can be expected[1]. The amount of Profilnine required to establish hemostasis will vary with each patient and circumstance. Use the following formula and example as guides in determining the number of units to be administered:

Body weight (in kg)	X	Desired increase in Plasma Factor IX (Percent)	X	1 Units/kg	=	Number of Factor IX Units Required
Example:						
50 kg	X	25 (% increase)	X	1 Units/kg	=	1,250 Units of factor IX

Due to variability among patients and their clinical condition, monitor the factor IX level of each patient frequently during replacement therapy.

Table 2 below provides treatment guidelines for hemorrhagic events and surgery in patients with factor IX deficiency.

Table 2: Treatment Guidelines

Type of Bleeding or Surgical Procedure	Factor IX Level Required, % of Normal (Dose)	Frequency of Doses	Duration of Therapy (Days)
Minor to Moderate Hemorrhages	20-30% (20-30 IU FIX/kg) until hemorrhage stops and healing has been achieved.	Every 16-24 hrs	Minor: 1-2 days Moderate: 2-7 days
Major	30-50% (30-50 IU	Every 16-24 hrs	3-10 days

Hemorrhages	FIX/kg). Following this treatment period, maintain FIX levels at 20% (20 IU FIX/kg) until healing has been achieved.		
Surgery	Prior to surgery, 30-50% (30-50 IU FIX/kg). For dental extractions, bring FIX levels to 50% immediately prior to the procedure. Maintain FIX levels at 30-50% (30-50 IU FIX/kg) until healing has been achieved.	Every 16-24 hrs	7-10 days

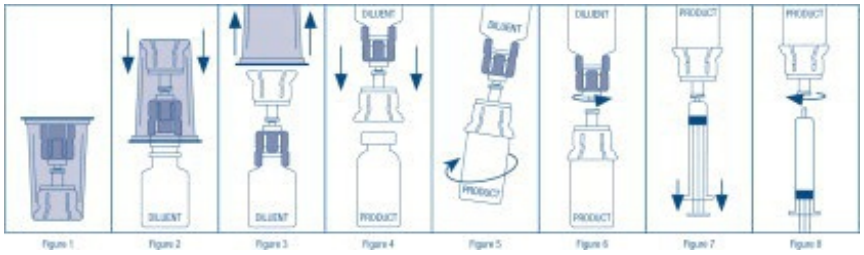
Dosing requirements and frequency of dosing are calculated on the basis of an initial response of 1% FIX increase achieved per IU of FIX infused per kg body weight and an average half-life for FIX of 24 hours. If dosing studies reveal that a particular patient exhibits a lower response, monitor blood levels and adjust the dose accordingly.

Reconstitution

Use Aseptic Technique

1. Ensure that concentrate (Profilnine) and diluent (Sterile Water for Injection, USP) are at room temperature (but not above 37° C) before reconstitution.
2. Remove the plastic flip off cap from the diluent vial.
3. Gently swab the exposed stopper surface with a cleansing agent such as alcohol. Avoid leaving any excess cleansing agent on the stopper.
4. Open the Mix2Vial® package by peeling away the lid (Figure 1). Leave the Mix2Vial in the clear outer packaging.
5. Place the diluent vial upright on an even surface, hold the vial tightly, and pick up the Mix2Vial in its clear outer packaging. While holding the diluent vial securely, push the **blue** end of the Mix2Vial vertically down through the diluent vial stopper (Figure 2).
6. While holding onto the diluent vial, carefully remove the clear outer packaging from the Mix2Vial set, ensuring the Mix2Vial remains attached to the diluent vial (Figure 3).
7. Place the product vial upright on an even surface, invert the diluent vial with the Mix2Vial attached.
8. While holding the product vial securely on a flat surface, push the **clear** end of the Mix2Vial set **vertically** down through the product vial stopper (Figure 4). The diluent will automatically transfer out of its vial into the product vial.
   NOTE: If the Mix2Vial is connected at an angle, the vacuum may be released from the product vial and the diluent will not transfer into the product vial.

9. With the diluent and product vials still attached to the Mix2Vial, gently swirl the product vial to ensure the product is fully dissolved (Figure 5). Reconstitution requires less than 10 minutes. Do not shake the vial.
10. Disconnect the Mix2Vial into two separate pieces (Figure 6) by holding each vial adapter and twisting counterclockwise. After separating, discard the diluent vial with the **blue** end of the Mix2Vial.
11. Draw air into an empty, sterile syringe. Keeping the product vial upright with the **clear** end of the Mix2Vial attached, screw the disposable syringe onto the luer lock portion of the Mix2Vial device by pressing and twisting clockwise. Inject air into the product vial.
12. While keeping the syringe plunger depressed, invert the system upside down and draw the reconstituted product into the syringe by pulling the plunger back slowly (Figure 7).
13. When the reconstituted product has been transferred into the syringe, firmly hold the barrel of the syringe and the clear vial adapter (keeping the syringe plunger facing down) and unscrew the syringe from the Mix2Vial (Figure 8). Hold the syringe upright and push the plunger until no air is left in the syringe. Attach the syringe to a venipuncture set.
    NOTE: If the same patient is to receive more than one vial of concentrate, the contents of two vials may be drawn into the same syringe through a separate unused Mix2Vial set before attaching to the venipuncture set.
14. After reconstitution, inspect parenteral drug products visually for particulate matter and discoloration prior to administration, whenever solution and container permit. When reconstitution procedure is strictly followed, a few small particles may occasionally remain. The Mix2Vial set will remove particles and the labeled potency will not be reduced.
15. Do not refrigerate after reconstitution. The reconstituted product is stable for 3 hours at room temperature; use as soon as possible within 3 hours after reconstitution.



Administration

For intravenous administration only,

- Inspect the final solution visually for particulate matter and discoloration prior to administration.
- Administer the prepared drug at room temperature within three hours after reconstitution. Prompt administration is recommended to avoid ill effects of any inadvertent bacterial contamination occurring during reconstitution.
- Administer by intravenous injection (plastic disposable syringe only) or infusion at a rate not exceeding 10 mL/minute.
- Discard any unused Profilnine vial contents. Discard administration equipment into

the appropriate safety container after single use. Do not resterilize components. Do not reuse components.

HOW SUPPLIED

Profilnine is supplied in sterile lyophilized form in single-dose vials accompanied by a suitable volume of diluent(Sterile Water for Injection, USP), according to factor IX potency. Each vial is labeled with the factor IX potency expressed in International Units which is referenced to the WHO International Standard. Profilnine is packaged with a Mix2Vial filter transfer set for use in administration.

The product is available in several potencies, with carton and vial label color coded based upon assay as follows:

Potency	Carton NDC	Assay Color Code
500 units FIX/5 mL	68516-3210-1 or 68516-3207-1	500 units FIX Range - gray box
1000 units FIX/10 mL	68516-3211-2 or 68516-3208-2	1000 units FIX Range - green box
1500 units FIX/10 mL	68516-3212-2 or 68516-3209-2	1500 units FIX Range - blue box

The diluent vial stopper contains natural rubber latex. All other components of the kit are not made with natural rubber latex.

STORAGE

Profilnine is stable for three years, up to the expiration date printed on its label, provided that the storage temperature does not exceed 25 °C (77 °F). Do not freeze.

Rx only

REFERENCES

1. Menache, D., Roberts, H.R. Summary report and recommendations of the task force members and consultants. *Thromb Diath Haemorrh* 33:645-647, 1975.
2. Kingdon, H.S., Lundblad, R.L., Veltkamp, J.J., Aronson, D.L. Potentially thrombogenic materials in Factor IX Concentrates. *Thromb Diath Haemorrh* 33:617- 631, 1975.
3. Burnouf T, Radosevich M. Nanofiltration of plasma-derived biopharmaceutical products. Haemophilia : the official journal of the World Federation of Hemophilia. 2003;9:24-37.
4. Dichtelmüller HO, Biesert L, Fabbrizzi F, Gajardo R, Gröner A, von Hoegen I, Jorquera JI, Kempf C, Kreil TR, Pifat D, Osheroff W, Poelsler G. Robustness of solvent/detergent treatment of plasma derivatives: a data collection from Plasma Protein Therapeutics Association member companies. Transfusion 49:1931-1943, 2009.
5. Sorensen, B., Spahn, D.R., Innerhofer, P., Spannagl, M., Rossaint, R. Clinical review: prothrombin complex concentrates-evaluation of safety and thrombogenicity. Critical Care 15: 201-209, 2011.

Manufactured by:
Grifols Biologicals LLC
5555 Valley Boulevard
Los Angeles, CA 90032, U.S.A.
U.S. License No. 1694
DATE OF REVISION: November 2022

3063695

Principal Display Panel – 500 IU Vial Label

NDC 68516-3204- 1 **500 IU FIX Range**

Factor IX Complex

Profilnine®

Storage: Store at temperatures not exceeding 25 °C (77 °F).
Rx Only. Single dose container for intravenous administration only.

5 mL

GRIFOLS U.S. License No. 1694

Instructions: Reconstitute with 5 mL Sterile Water for Injection, USP. Administer intravenously at room temperature within three hours of reconstitution. Discard unused contents. Contains Factors II, IX, X, and low levels of Factor VII. Contains no preservatives. For information on dosage and directions for administration, see accompanying pamphlet. The patient and physician should discuss the risks and benefits of this product.

Grifols Biologicals LLC
5555 Valley Boulevard,
Los Angeles, CA 90032, U.S.A.

Lot

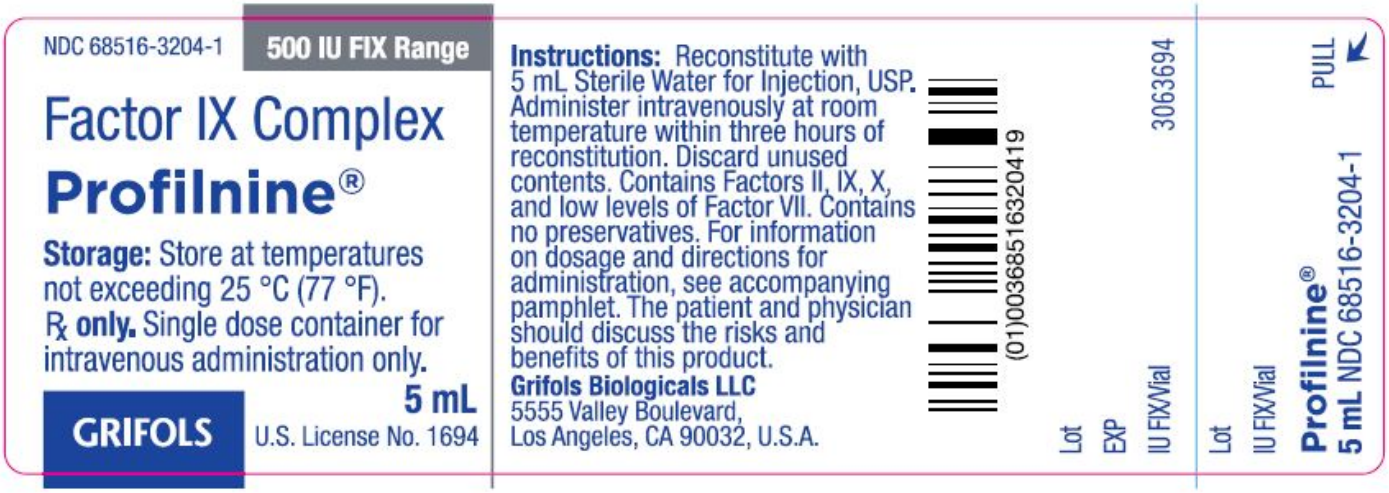
EXP

IU FIX/Vial 3063694

Lot

IU FIX/Vial

Profilnine®
5 mL NDC 68516-3204-1



Principal Display Panel 500 IU Carton Label

NDC 68516-3210-1 **500 IU FIX Range**

Factor IX Complex
Profilnine®

For Intravenous Administration 5 mL

GRIFOLS

Contents:
One vial Factor IX Complex, Profilnine®, one vial 5 mL Sterile Water for Injection, USP, one Mix2Vial® filter transfer set, and directions for use. Contains Factors II, IX, X and low levels of Factor VII.

The reconstituted product contains not more than 2.5 µg polysorbate 80 and 0.40 µg tri (n-butyl) phosphate per IU of Factor IX.

Contains no preservatives.

Administer within three hours of reconstitution. Discard unused contents.

GRIFOLS

Warning: This product is prepared from large pools of human plasma. Human blood and its components may transmit infectious agents. See package insert, WARNINGS AND PRECAUTIONS.

Instructions: The patient and physician should discuss the risks and benefits of this product. For information on dosage and directions for administration, see enclosed package insert.

Storage: Store at temperatures not exceeding 25 °C (77 °F). Do not freeze.

Rx only. Single dose container for intravenous administration only.

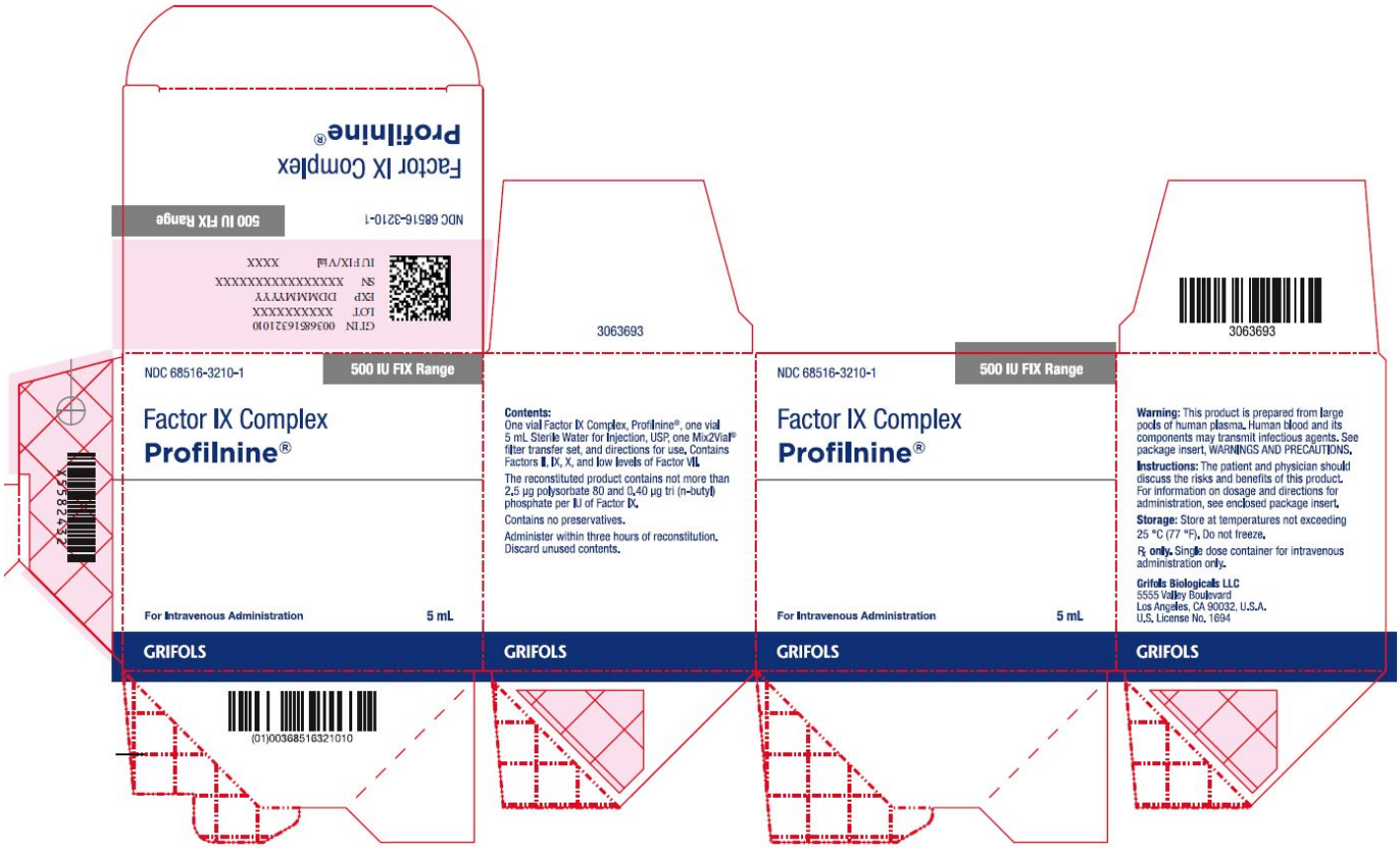
Grifols Biologicals LLC
5555 Valley Boulevard
Los Angeles, CA 90032, U.S.A.
U.S. License No. 1694

GRIFOLS

GTIN 00368516321010
LOT XXXXXXXXXX
EXP DDMMMYYYY
SN XXXXXXXX XXXXXXXX

IU FIX/Vial XXXX

3063693



Principal Display Panel – 1000 IU Vial Label

NDC 68516-3206-2 **1000 IU FIX Range**

Factor IX Complex

Profilnine®

Storage: Store at temperatures not exceeding 25 °C (77 °F).
Rx Only. Single dose container for intravenous administration only.

GRIFOLS

10 mL U.S. License No. 1694

Instructions: Reconstitute with 10 mL Sterile Water for Injection, USP. Administer intravenously at room temperature within three hours of reconstitution. Discard unused contents. Contains Factors II, IX, X, and low levels of Factor VII. Contains no preservatives. For information on dosage and directions for

administration, see accompanying pamphlet. The patient and physician should discuss the risks and benefits of this product.

Grifols Biologicals LLC
5555 Valley Boulevard,
Los Angeles, CA 90032, U.S.A.

Lot

EXP

IU FIX/Vial 3063692

Lot

IU FIX/Vial

Profilnine®
10 mL NDC 68516-3205-2

Principal Display Panel 1000 IU Carton Label

NDC 68516-3211-2 **1000 IU FIX Range**

Factor IX Complex
Profilnine®

For Intravenous Administration 10 mL

GRIFOLS

Contents: One vial Factor IX Complex, Profilnine®, one vial 10 mL Sterile Water for Injection, USP, one Mix2Vial® filter transfer set, and directions for use. Contains Factors II, IX, X and low levels of Factor VII.

The reconstituted product contains not more than 2.5 µg polysorbate 80 and 0.40 µg tri (n-butyl) phosphate per IU of Factor IX.

Contains no preservatives.

Administer within three hours of reconstitution. Discard unused contents.

GRIFOLS

Warning: This product is prepared from large pools of human plasma. Human blood and its components may transmit infectious agents. See package insert, WARNINGS AND PRECAUTIONS.

Instructions: The patient and physician should discuss the risks and benefits of this product. For information on dosage and directions for administration, see enclosed package insert.

Storage: Store at temperatures not exceeding 25 °C (77 °F). Do not freeze.

Rx only Single dose container for intravenous administration only.

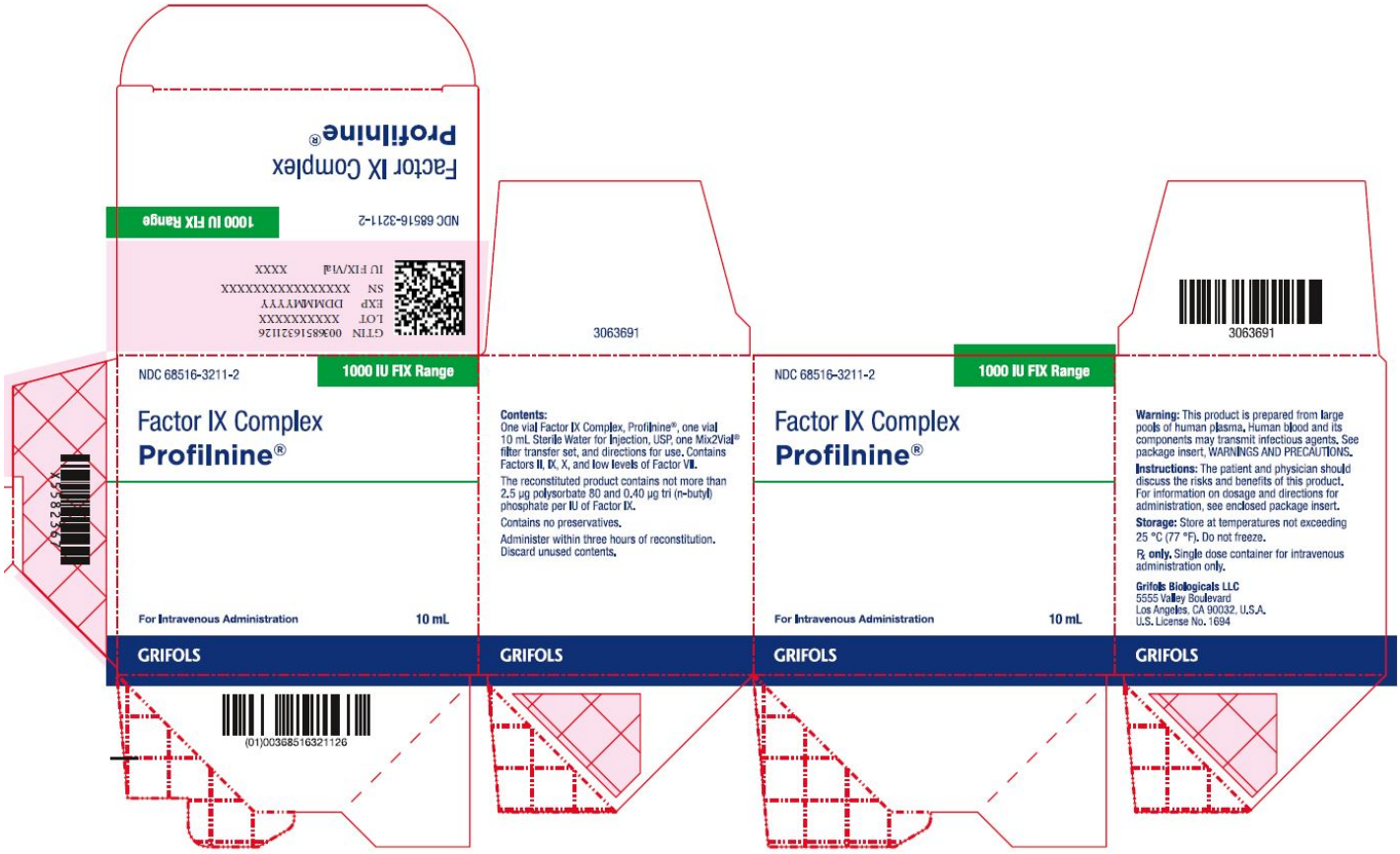
Grifols Biologicals LLC
5555 Valley Boulevard
Los Angeles, CA 90032, U.S.A.
U.S. License No. 1694

GRIFOLS

GTIN 00368516321126
LOT XXXXXXXXXX
EXP DDMMMYYYY
SN XXXXXXXXXXXXXXX

IU FIX/Vial XXXX

3063691



Principal Display Panel – 1500 IU Vial Label

NDC 68516-3206-2 **1500 IU FIX Range**

Factor IX Complex

Profilnine®

Storage: Store at temperatures not exceeding 25 °C (77 °F).
Rx Only. Single dose container for intravenous administration only.

10 mL

GRIFOLS U.S. License No. 1694

Instructions: Reconstitute with 10 mL Sterile Water for Injection, USP. Administer intravenously at room temperature within three hours of reconstitution. Discard unused contents. Contains Factors II, IX, X, and low levels of Factor VII. Contains no preservatives. For information on dosage and directions for

administration, see accompanying pamphlet. The patient and physician should discuss the risks and benefits of this product.

Grifols Biologicals LLC
5555 Valley Boulevard,
Los Angeles, CA 90032, U.S.A.

Lot

EXP

IU FIX/Vial 3063690

Lot

IU FIX/Vial

Profilnine®
10 mL NDC 68516-3206-2

Principal Display Panel 1500 IU Carton Label

NDC 68516-3212-2 **1500 IU FIX Range**

Factor IX Complex
Profilnine®

For Intravenous Administration 10 mL

GRIFOLS

Contents: One vial Factor IX Complex, Profilnine®, one vial 10 mL Sterile Water for Injection, USP, one Mix2Vial®

filter transfer set, and directions for use. Contains Factors II, IX, X and low levels of Factor VII.

The reconstituted product contains not more than 2.5 µg polysorbate 80 and 0.40 µg tri (n-butyl) phosphate per IU of Factor IX.

Contains no preservatives.

Administer within three hours of reconstitution. Discard unused contents.

Warning: This product is prepared from large pools of human plasma. Human blood and its components may transmit infectious agents. See package insert, WARNINGS AND PRECAUTIONS.

GRIFOLS

Instructions: The patient and physician should discuss the risks and benefits of this product. For information on dosage and directions for administration, see enclosed package insert.

Storage: Store at temperatures not exceeding 25 °C (77 °F). Do not freeze.

Rx only. Single dose container for intravenous administration only.

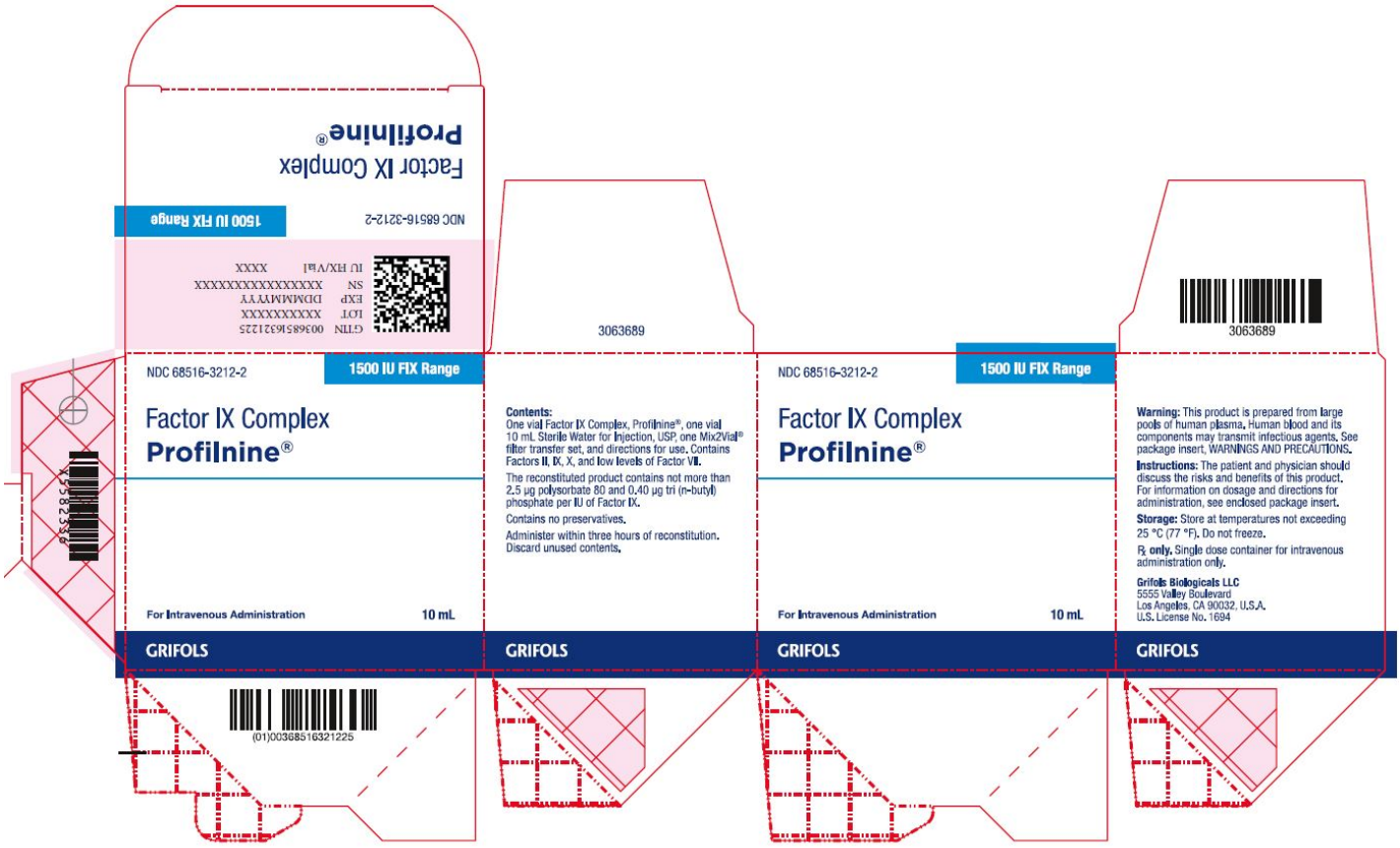
Grifols Biologicals LLC
5555 Valley Boulevard
Los Angeles, CA 90032, U.S.A.
U.S. License No. 1694

GRIFOLS

GTIN 00368516321225
LOT XXXXXXXXXX
EXP DDMMMYYYY
SN XXXXXXXXXXXXXXX

IU FIX/Vial XXXX

3063689



Principal Display Panel - 5 mL Vial Label

NDC 76297-002-02

Sterile Water for Injection, USP

5 mL

Rx Only

For reconstitution of accompanying product
Single-Dose Container, Nonpyrogenic

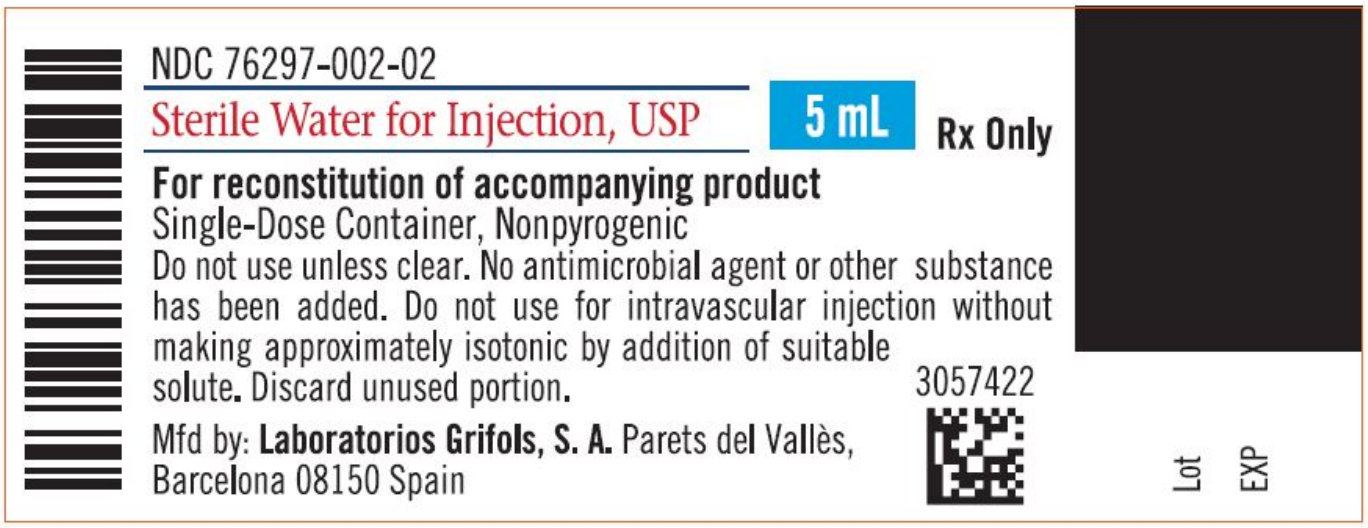
Do not use unless clear.
No antimicrobial agent or other substance has been added.
Do not use for intravascular injection without making approximately isotonic by addition of suitable solute.
Discard unused portion.

Mfd by: **Laboratorios Grifols, S. A.** Parets del Vallès,
Barcelona 08150 Spain

Lot

EXP

3057422



Principal Display Panel - 5 mL Vial Label

NDC 68516-1001-1

Sterile Water for Injection, USP

5 mL
Rx Only
For reconstitution of accompanying product
Single-Dose Container, Nonpyrogenic

Do not use unless clear.
No antimicrobial agent or other substance has been added.
Do not use for intravascular injection without making approximately isotonic by addition of suitable solute.
Discard unused portion.

Mfd by: **Laboratorios Grifols, S. A.** Parets del Vallès, Barcelona 08150 Spain
Mfd for: **Grifols Biologicals LLC** Los Angeles, CA90032, USA
Lot

EXP

3051532

Principal Display Panel - 10 mL Vial Label

NDC 76297-002-12

Sterile Water for Injection, USP

10 mL

Rx Only

For reconstitution of accompanying product
Single-Dose Container, Nonpyrogenic

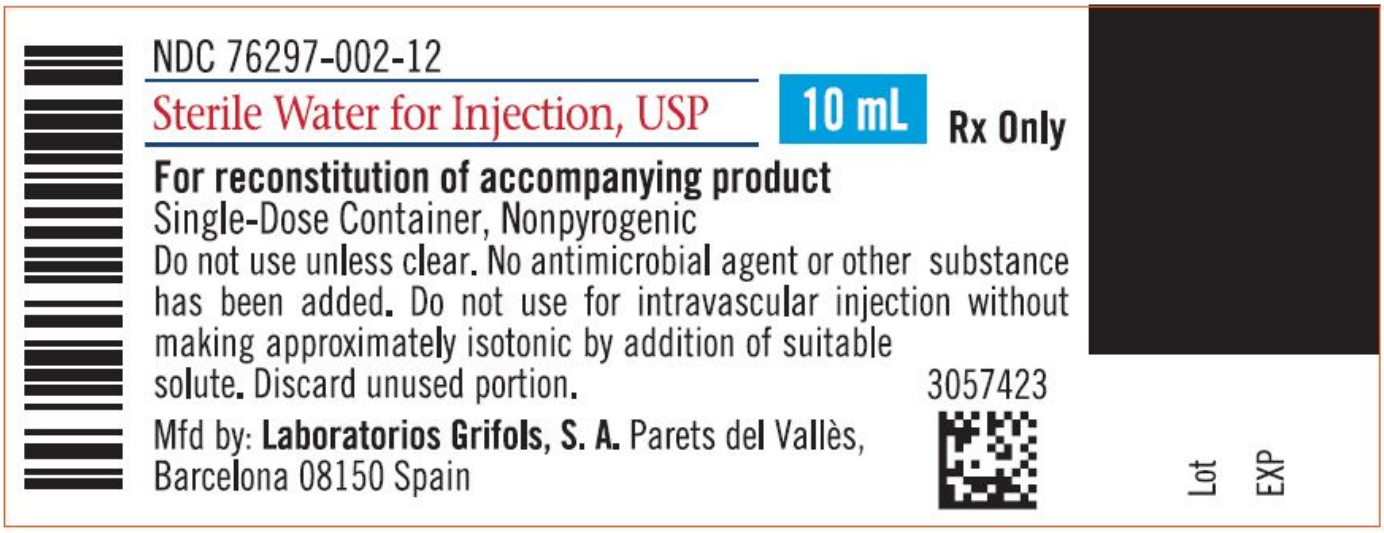
Do not use unless clear.
No antimicrobial agent or other substance has been added.
Do not use for intravascular injection without making approximately isotonic by addition of suitable solute.
Discard unused portion.

Mfd by: **Laboratorios Grifols, S. A.** Parets del Vallès,
Barcelona 08150 Spain

Lot

EXP

3057423



Principal Display Panel - 10 mL Vial Label

NDC 68516-1002-2

Sterile Water for Injection, USP

10 mL

Rx Only

For reconstitution of accompanying product
Single-Dose Container, Nonpyrogenic

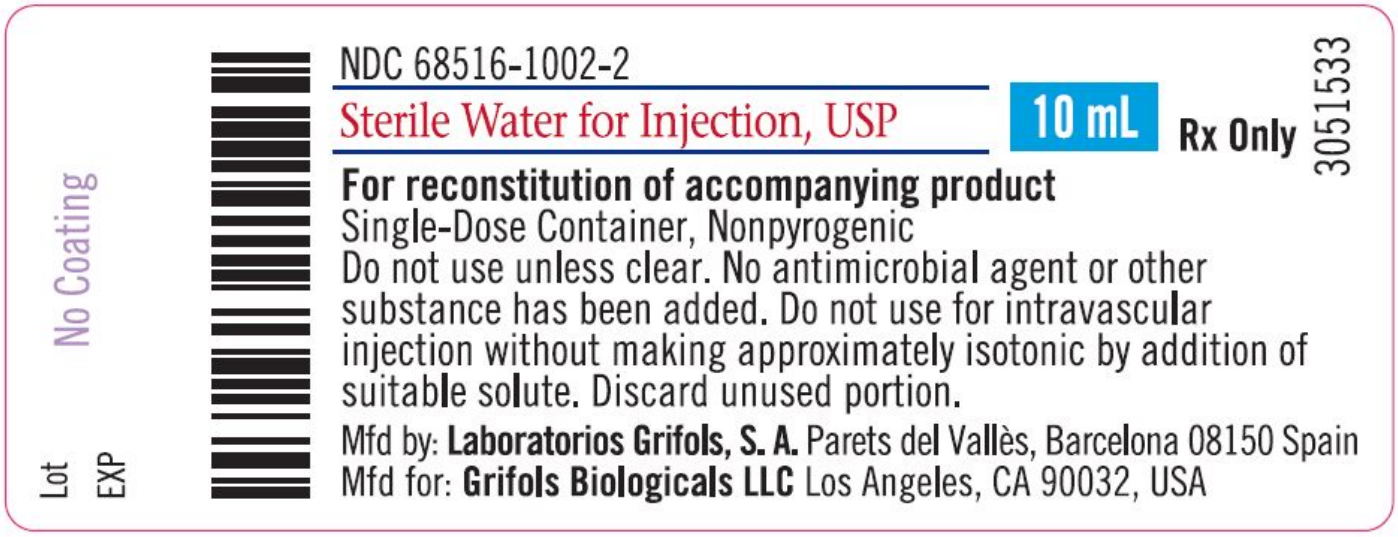
Do not use unless clear.
No antimicrobial agent or other substance has been added.
Do not use for intravascular injection without making approximately isotonic by addition of suitable solute.
Discard unused portion.

Mfd by: **Laboratorios Grifols, S. A.** Parets del Vallès,
Mfd for: **Grifols Biologicals LLC** Los Angeles, CA 90032, USA

Lot

EXP

3051533



PROFILNINE

factor ix complex kit

Product Information			
Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:68516-3207

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68516-3207-1	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 VIAL	5 mL
Part 2	1 VIAL, SINGLE-DOSE	5 mL

Part 1 of 2

PROFILNINE

factor ix complex injection, powder, lyophilized, for solution

Product Information	
Item Code (Source)	NDC:68516-3204
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
factor ix complex (UNII: FW411QXD5M) (factor ix complex - UNII:FW411QXD5M)	factor ix complex	500 [iU] in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
sodium chloride (UNII: 451W47IQ8X)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
sodium phosphate (UNII: SE337SVY37)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68516-3204-1	5 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

Part 2 of 2

STERILE WATER

water injection

Product Information	
Item Code (Source)	NDC:68516-1001
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)	water	1 mL in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68516-	5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a		

1	1001-1	Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

PROFILNINE

factor ix complex kit

Product Information

Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:68516-3210

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68516-3210-1	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL	5 mL
Part 2	1 VIAL, GLASS	5 mL

Part 1 of 2

PROFILNINE

factor ix complex injection, powder, lyophilized, for solution

Product Information

Item Code (Source)	NDC:68516-3204
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
factor ix complex (UNII: FW411QXD5M) (factor ix complex - UNII:FW411QXD5M)	factor ix complex	500 [iU] in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
sodium chloride (UNII: 451W47IQ8X)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
sodium phosphate (UNII: SE337SVY37)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68516-3204-1	5 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

Part 2 of 2

STERILE WATER

water solution

Product Information	
Item Code (Source)	NDC:76297-002
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)	water	1 mL in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76297-	5 mL in 1 VIAL, GLASS; Type 0: Not a Combination		

1	002-02	Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/15/1978	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

PROFILNINE

factor ix complex kit

Product Information

Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:68516-3208

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68516-3208-2	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL	10 mL
Part 2	1 VIAL, SINGLE-DOSE	10 mL

Part 1 of 2

PROFILNINE

factor ix complex injection, powder, lyophilized, for solution

Product Information

Item Code (Source)	NDC:68516-3205
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
factor ix complex (UNII: FW411QXD5M) (factor ix complex - UNII:FW411QXD5M)	factor ix complex	1000 [iU] in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
sodium chloride (UNII: 451W47IQ8X)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
sodium phosphate (UNII: SE337SVY37)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68516-3205-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

Part 2 of 2

STERILE WATER

water injection

Product Information	
Item Code (Source)	NDC:68516-1002
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)	water	1 mL in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:68516-1002-2	10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

PROFILNINE

factor ix complex kit

Product Information

Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:68516-3211

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68516-3211-2	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL	10 mL
Part 2	1 VIAL, GLASS	10 mL

Part 1 of 2

PROFILNINE

factor ix complex injection, powder, lyophilized, for solution

Product Information

Item Code (Source)	NDC:68516-3205
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
factor ix complex (UNII: FW411QXD5M) (factor ix complex - UNII:FW411QXD5M)	factor ix complex	1000 [iU] in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
sodium chloride (UNII: 451W47IQ8X)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
sodium phosphate (UNII: SE337SVY37)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68516-3205-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

Part 2 of 2

STERILE WATER

water solution

Product Information	
Item Code (Source)	NDC:76297-002
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)	water	1 mL in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:76297-002-12	10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/15/1978	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

PROFILNINE

factor ix complex kit

Product Information

Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:68516-3209

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68516-3209-2	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL	10 mL
Part 2	1 VIAL, SINGLE-DOSE	10 mL

Part 1 of 2

PROFILNINE

factor ix complex injection, powder, lyophilized, for solution

Product Information

Item Code (Source)	NDC:68516-3206
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
factor ix complex (UNII: FW411QXD5M) (factor ix complex - UNII:FW411QXD5M)	factor ix complex	1500 [iU] in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
sodium chloride (UNII: 451W47IQ8X)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
sodium phosphate (UNII: SE337SVY37)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68516-3206-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

Part 2 of 2

STERILE WATER

water injection

Product Information	
Item Code (Source)	NDC:68516-1002
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)	water	1 mL in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:68516-1002-2	10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

PROFILNINE

factor ix complex kit

Product Information

Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:68516-3212

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68516-3212-2	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL	10 mL
Part 2	1 VIAL, GLASS	10 mL

Part 1 of 2

PROFILNINE

factor ix complex injection, powder, lyophilized, for solution

Product Information

Item Code (Source)	NDC:68516-3206
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
factor ix complex (UNII: FW411QXD5M) (factor ix complex - UNII:FW411QXD5M)	factor ix complex	1500 [iU] in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
sodium chloride (UNII: 451W47IQ8X)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
sodium phosphate (UNII: SE337SVY37)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68516-3206-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

Part 2 of 2

STERILE WATER

water solution

Product Information	
Item Code (Source)	NDC:76297-002
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)	water	1 mL in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:76297-002-12	10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/15/1978	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102476	07/20/1981	

Labeler - GRIFOLS USA, LLC (048987452)

Establishment

Name	Address	ID/FEI	Business Operations
Grifols Biologicals LLC		121076871	manufacture(68516-3207, 68516-3208, 68516-3209, 68516-3210, 68516-3211, 68516-3212)

Establishment

Name	Address	ID/FEI	Business Operations
LABORATORIOS GRIFOLS SA		463719725	manufacture(68516-1001, 68516-1002, 76297-002)

Establishment

Name	Address	ID/FEI	Business Operations
GRIFOLS BIOLOGICALS LLC		092694538	manufacture(68516-3207, 68516-3208, 68516-3209, 68516-3210, 68516-3211, 68516-3212)

Revised: 6/2023 GRIFOLS USA, LLC