Mononine® is a highly purified preparation of Factor IX. When stored as directed, it will maintain its labeled potency for the period indicated on the container label. Each vial contains the labeled amount of Factor IX activity expressed in International Units (IU). One IU represents the amount of Factor IX activity expected to clot approximately 0.01 mL of normal plasma within one hour at 37°C.

Mononine® is purified of extraneous plasma-derived proteins, including Factors II, VII, IX, and X. By use of immunofinity chromatography a murine monoclonal antibody to Factor IX is used as an affinity ligand to isolate Factor IX from the source material. Factor IX is then dissociated from the monoclonal antibody using a second, specific antibody chemically linked to the bead, and chemically purified to obtain Factor IX activity identical to that found in normal plasma.

Mononine® contains trace amounts of the murine monoclonal antibody (MAB) used in its purification (≤0.5 ng mouse protein/100 IU). While the levels of mouse protein are extremely low, infusion of such proteins might theoretically induce human anti-mouse antibodies. Patients undergoing treatment with Mononine® are carefully monitored for evidence of disseminated intravascular coagulation. In six subjects evaluated after infusion, fibrinogen levels and platelet counts were unchanged, and fibrinopeptide products did not appear.

Clinical studies. The safety and efficacy of using Mononine® in attempted immune tolerance induction has not been established. The safety and efficacy of using Mononine® in attempted immune tolerance induction has not been established.

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Pregnancy Category C - followed by nausea, vomiting and pain in the belly. Dark urine and a yellowed complexion are also derived products to report potential symptoms promptly.

If symptoms occur.

Some viruses such as hepatitis A are particularly difficult to remove or inactive at this time. Although the overwhelming number of hepatitis A cases are community acquired, there have been reports of these infections associated with the use of some plasma-derived products. Therefore, physicians should be alert to the potential symptoms of hepatitis A infections and inform patients under their supervision receiving plasma-derived products to report potential symptoms promptly. Evidence of hepatitis A may include several days to weeks of poor appetite, tiredness, and low-grade fever followed by nausea, vomiting and pain in the belly. Dark urine and a yellowed complexion are also common symptoms. Patients should be encouraged to consult their physicians if such symptoms occur.

Pregnancy Category C - Animal reproduction studies have not been conducted with Mononine®. It is also not known whether Mononine® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Mononine® should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

As with the majority of administration of other plasma-derived products, the following reactions may be observed following administration: headache, fever, chills, flushing, nausea, vomiting, tingling, leucocyte, hives, stinging or burning at the infusion site or manifestations of allergic reactions. In a clinical study with Mononine® in previously untreated hemophilia B patients, five patients experienced ALT elevations. Serologic tests for hepatitis A, hepatitis B, hepatitis C, Cytomegalovirus, and Epstein-Barr virus were negative. These adverse reactions have been spontaneously reported during post-marketing use of Mononine® as well as other Factor IX products: anaphylaxis, angioedema, cyanosis, dyspnea, hypotension, anaphylactic, hypotension, thrombosis, inadequately therapeutic response, and inhibitor development.

There is a potential risk of thrombembolic episodes following the administration of Mononine® (see WARNINGS and PRECAUTIONS).

The patient should be monitored closely during the infusion of Mononine® to observe for the development of any reaction. If any reaction takes place that is thought to be related to the administration of Mononine®, the rate of infusion should be decreased or the infusion stopped, as dictated by the response of the patient.

PROPHYLAXIS OR SURGERY

To achieve the desired level of Factor IX activity, the infusion rate should be adjusted, if necessary, to maintain the desired concentration. The dosage regimen should be individualized and will vary for different patients. The recommended dosage regimen is as described below. Each product package consists of the following:

The manufacturer’s name is stated on the label of each vial.

CSL Behring LLC

Mononine® are available. 

Each product package consists of the following:

The manufacturer’s name is stated on the label of each vial.

For information on rate of administration, see Rate of Administration, below.

Reconstitution

1. Remove the caps from both vials to expose the central portions of the rubber stoppers.

2. Treat the surface of the antibiotic silica gel and allow them to dry.

3. Using aseptic technique, attach the vented filter spike to a sterile disposable syringe.

CAUTION: The use of other, non-vented filter spikes or needles without the procedure may result in an air lock and prevent the complete transfer of the concentrate.

CAUTION: DO NOT INJECT AIR INTO THE MONONINE® VIAL. The self-sealing feature of the vented filter spike allows for aseptic handling and facilitates withdrawal of the reconstituted solution. The injection of air could cause partial product loss through the filter.

4. Insert the vented filter spike into the stopper of the Mononine® vial, invert the vial, and position the filter spike so that the orifice is at the inside edge of the stopper.

5. Withdraw the reconstituted solution into the syringe.

6. Discard the filter spike. Perform the procedure with the enclosed winged needle with microbore tubing. Attach the syringe to the end of the tubing.

CAUTION: Use of other winged needles without microbore tubing, although compatible with the concentrate, will result in a larger retention of solution within the withdrawn infusion set.

Rate of Administration

The rate of administration should be determined by the response and comfort of the patient; intravenous dose and infusion rates of up to 2.25 mL/min have been reported without incident. When reconstituted as directed, i.e., to approximately 100 IU/mL, Mononine® should be administered at a rate of approximately 2.0 mL per minute.

STORAGE

When stored at refrigerated temperature, 2-8°C (36-46°F), Mononine® is stable for the period indicated by the expiration date on its label. Within this period, Mononine® may be stored at room temperature not to exceed 25°C (77°F), for up to one month.

Avoid freezing, which may damage container for the diluent.

HOW SUPPLIED

Mononine® is supplied in a single dose vial with Sterile Water for Injection, USP, double-ended needle for reconstitution, vented filter spike for withdrawal, withdrawn infusion set and alcohol swabs. Factor IX activity in IU is stated on the label of each vial.

Each product package consists of the following:

NDC Number

Component

Approximate Fix Activity (IU)

500 (MDR)

500-6323-02

Factor (k1) containing one vial of Mononine® (NDC 0053-6242-01), one 5 mL vial of Sterile Water for Injection, USP (NDC 7653-06), one double-ended needle for reconstitution, one vented filter spike for withdrawal, one withdrawn infusion set, and alcohol swabs.

1000 (HIGH)

500-6323-03

Factor (k1) containing one vial of Mononine® (NDC 0053-6243-01), one 10 mL vial of Sterile Water for Injection, USP (NDC 7653-71), one double-ended needle for reconstitution, one vented filter spike for withdrawal, one withdrawn infusion set, and alcohol swabs.


Manufactured by:

CSL Behring LLC

Kankakee, IL 60901 USA

US License No. 1767

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