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 1.00 ± 0.05 mg (mouse protein/100 Factor IX activity units) of the murine monoclonal antibody used in the immunooaffinity protocol utilized results in a highly pure Factor IX preparation. It shows predominantly a single component by SDS polyacrylamide electrophoresis and has a specific activity of not less than 190 Factor IX units per mg of protein. All Source Plasma used in the manufacture of this product was tested by FDA-licensed Nucleic Acid Tests (NAT) for HCV and HIV-1 and found to be nonreactive (negative).

Mononine® is purified of extraneous plasma-derived proteins, including Factors II, VII, and X by use of immunoaffinity 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 by a highly purified preparation of extraneous plasma-derived proteins, including Factors II, VII, and X by use of immunoaffinity 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 by a mild alkaline elution buffer. Mononine® is produced by a process that utilizes a specific immunoaffinity protocol and the virus hepatitis serology tests did not reveal any abnormalities. In addition, in one of these subjects, the ALT level was slightly above the upper limit of normal (65 IU/L upper limit of normal). Thirty-seven (37) subjects (30 with moderate to severe deficiency and seven with a mild deficiency) of the Mononine® cohort were investigated thoroughly and none of the ALT elevations were found to be related to viral hepatitis. In one of these subjects, the ALT level was slightly above the upper limit of normal (65 IU/L upper limit of normal). Thirty-seven (37) subjects (30 with moderate to severe deficiency and seven with a mild deficiency) of the Mononine® cohort were investigated thoroughly and none of the ALT elevations were found to be related to viral hepatitis.
Pregnancy Category C - derived products to report potential symptoms promptly. Potential symptoms of hepatitis A infections and inform patients under their supervision receiving plasma-

As with the intravenous administration of other plasma-derived products, the following reactions may be increased risk for inhibitor formation and acute hypersensitivity reactions. (See WARNINGS.)

The use of high doses of Factor IX Complex concentrates has been reported to be associated with instances of myocardial infarction, disseminated intravascular coagulation, venous thrombosis and pulmonary embolism. Generally a Factor IX level of 25-50% (40 IU/dL) is considered adequate for hemostasis, including major hematomas and surgery. Attempting to maintain Factor IX levels of >75-100% (IU/dL) during treatment is not routinely recommended nor required. To achieve Factor IX levels that will remain above 25% (40 IU/dL) between one day administrations, each daily dose should be raised by 30-50% of the post-infusion Factor IX level to 50-60% (IU/dL) (See DOSAGE AND ADMINISTRATION).

No controlled studies have been available regarding the use of deaminocaproic acid or other antifibrinolytic agents following an initial infusion of Mononine® for the prevention of treatment failure following trauma or dental procedures such as extractions.

Information For Patients - Patients should be informed of the early symptoms and signs of hypersensitivity reactions including, but not limited to, urticaria, flushing, tightness of the chest, dyspnea, wheezing, faintness, hypotension, and anaphylaxis. Patients should be advised to discontinue use of the product and contact their physician and/or seek immediate emergency care, depending on the severity of the reaction, if any symptoms occur.

Some viruses such as hepatitis A are particularly difficult to remove or inactivate at this time. Although the overwhelming number of hepatitis A cases are currently 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.

Evidences 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 yellow complexion are also common symptoms. Patients should be encouraged to inform 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.

Pediatric Use - Evaluation of the safety and effectiveness of Mononine® treatment in 51 pediatric patients between the ages of 1 day and 20 years, as a part of virus safety trials and for trials, trauma or spontaneous bleeding, showed the safety and effectiveness of Mononine® with no thrombotic complications. It included in the experience with patients aged 20 to 2 years are two long-term virus safety studies demonstrating lack of virus transmission. Dosing in children is based on body weight and is generally based on the same guidelines as for adults (See DOSAGE AND ADMINISTRATION).

Geriatric Use - Clinical studies of Mononine® did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. As all patients, dosing for geriatric patients should be appropriate to their overall situation.

Adverse Reactions As with the intravenous administration of other plasma-derived products, the following reactions may be observed following administration: headache, fever, chillis, flushing, nausea, vomiting, tingling, leucogry, hives, stingng or burning at the injection site or manifestations of allergic reactions. In a clinical study with Mononine® patients received Factor IX concentrates with no thrombotic complications. It included in the experience with patients aged 20 to 2 years are two long-term virus safety studies demonstrating lack of virus transmission. Dosing in children is based on body weight and is generally based on the same guidelines as for adults (See DOSAGE AND ADMINISTRATION).

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