

**Coagulation Factor IX (Human), MONONINE®, Monoclonal Antibody
Purified**

IMPORTANT SAFETY INFORMATION

INDICATIONS AND IMPORTANT SAFETY INFORMATION

MONONINE®, Coagulation Factor IX (Human), is indicated for the prevention and control of bleeding in Factor IX deficiency, also known as hemophilia B or Christmas disease.

Mononine® is not indicated in the treatment or prophylaxis of Hemophilia A patients with inhibitors to Factor VIII.

MONONINE is contraindicated in patients with known hypersensitivity to mouse proteins.

The following reactions may be observed following administration: headache, fever, chills, flushing, nausea, vomiting, tingling, lethargy, hives, stinging or burning at the infusion site, or other manifestations of allergic reactions, including anaphylaxis.

MONONINE is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

Since the use of Factor IX Complex concentrates has historically been associated with the development of thromboembolic complications, the use of Factor IX-containing products may be potentially hazardous in patients with signs of fibrinolysis and in patients with disseminated intravascular coagulation (DIC).

Please see accompanying full prescribing information for MONONINE.