Protamine Sulphate Injection BP

MIMS Abbreviated Prescribing Information
Protamine sulfate
Aventis Pharma
Section: 2(l) Haemostatic agents - Cardiovascular System
Pregnancy Category: B2
Permitted in sport

Use: Counteracts anticoagulant effect of heparin
Precautions: Pregnancy, lactation, children
Adverse Reactions: Hypotension; allergy esp if previous exposure, exposure to protamine insulin, fish allergy, infertile or vasectomised men

Protamine Sulphate Injection BP Rx (S4) CMI
Protamine sulfate; amp
Pack 1% 5 mL [10]
Dose 1 mg slow IVI neutralises approx. 100 IU mucous heparin; max. single dose 50 mg (5 mL)

Protamine Sulfate Injection BP

MIMS Full Prescribing Information
MIMS revision date: 1/05/1999
Composition Active. Protamine sulfate (salmine).
Inactive. Sodium Chloride Intravenous Infusion BP, adjusted to pH 2.5 to 3.5, hydrochloric acid, sodium hydroxide, water for injections.

Actions Protamine is a basic protein which combines with heparin to form a stable, inactive complex.
Indications To counteract the anticoagulant effect of heparin before surgery; after renal dialysis; after open heart surgery; if excessive bleeding occurs; and when an overdose has inadvertently been given.
Warnings Too rapid administration of protamine sulphate may cause severe hypotension and anaphylactoid reactions.
Facilities for resuscitation and treatment of shock should be available.
Not more than 50 mg protamine sulfate, i.e. one ampoule 5 mL Protamine Sulfate Injection BP 1%, should be given at any one time.
Protamine is not suitable for reversing the effect of oral anticoagulants. Caution should be observed when administering protamine sulfate to patients who may be at increased risk of allergic reaction to protamine. These patients include those who have previously undergone procedures such as coronary angioplasty or cardiopulmonary bypass which may include use of protamine, diabetics who have been treated with protamine insulin, patients allergic to fish, and men who have had a vasectomy or are infertile and may have antibodies to protamine.
Patients undergoing prolonged procedures involving repeated doses of protamine should be subject to careful monitoring of clotting parameters. A rebound bleeding effect may occur up to 18 hours postoperatively which responds to further doses of protamine.
Precautions Use in pregnancy. (Category B2)
Use in lactation. As with most drugs, to be used only if clearly indicated with caution during lactation.
Use in children. Safety and efficacy in children have not been established, therefore use in children is not recommended.
Interactions None known.
Adverse Reactions When used at doses in excess of that required to neutralise the anticoagulant effect of heparin, protamine sulfate exerts its own anticoagulant effect. Following injection of protamine sulfate the following effects have been observed: sudden fall in blood pressure, bradycardia, pulmonary and systemic hypertension, dyspnoea, transitory flushing and a feeling of warmth, back pain, nausea and vomiting, lassitude.
Hypersensitivity reactions and fatal anaphylaxis have been reported.
Dosage and Administration Protamine Sulfate Injection should be administered by slow intravenous injection over a period of about 10 minutes.
The dose is dependent on the amount of heparin that has to be neutralised; protamine sulfate 1 mg will usually neutralise mucous heparin 100 IU or lung heparin 80 IU. Since heparin is being continuously excreted, the dose should be reduced if more than 15 minutes have elapsed since the heparin injection. Ideally, the dose required to neutralise the action of heparin should be calculated from the results of determinations of the amount required to produce an acceptable blood clotting time in the patient. In gross excess, protamine itself acts as an anticoagulant.
Overdosage Symptoms. Overdosage may cause hypotension, bradycardia and dyspnoea with a sensation of warmth, nausea, vomiting, lassitude and transitory flushing.
Treatment. Includes monitoring of coagulation tests, respiratory ventilation and symptomatic treatment. If bleeding is a problem, fresh frozen plasma or fresh whole blood should be given.
Presentation Ampoules, 10 mg/mL, 5 mL: 10's.
Poison Schedule S4.
Date of TGA approval or last amendment 16/12/1997
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