PRECAUTIONS AND WARNINGS

A low incidence of adverse reactions is experienced with KRYOBULIN, but the following may occur:

All forms of allergic reaction from mild and transient urticaria to severe anaphylactic shock are possible when human plasma derivatives are administered. If such reactions occur, treatment with KRYOBULIN must be interrupted at once. Allergic reactions should be controlled with antihistamines and routine treatment given for anaphylactic shock. Monitoring of pulse rate and blood pressure is essential. If the pulse rate increases and/or blood pressure falls, transfusion of 5% Dextrose should be started.

The appearance of a circulating Factor VIII inhibitor is possible. Its appearance cannot be predicted as it does not relate to the amount of KRYOBULIN administered, nor to the frequency of administration. As far as is known neither corticosteroids nor immunosuppressive agents significantly influence the formation of inhibitors.

In patients with a history of hypersensitivity reactions to plasma derivatives the prophylactic administration of antihistamines may be indicated.

If massive doses of non blood group compatible KRYOBULIN are administered over a short period of time, haemolytic reactions may occur. In severe cases of haemolysis and anaemia type O whole blood or red blood concentrates should be administered.

After administration of unusually high doses as may be required in patients with Factor VIII inhibitors, the risk of hypervolaemia must be taken into consideration.

The careful selection of donors and plasma and the vapour heat treatment process which has been shown capable of reducing artificially introduced HTLV-III by 6 log steps, suggests that in the light of present knowledge the transmission of HTLV-III can be excluded.

The above measures will certainly reduce the risk of transmission of viral hepatitis. This is being demonstrated by the fact that upwards of 20 naive patients have been followed up by ALT tests for 4 months and have not acquired NANB infection but transmission of Hepatitis cannot be entirely ruled out.

INTERACTIONS

None known

SHELF LIFE AND STORAGE

Two years when stored between + 2° and + 8°C.

Within the indicated shelf life period the product may be stored for 6 months at room temperature (max. 30°C). Even without cooling facilities KRYOBULIN can therefore be taken on extended journeys.

The dates between which the product is not stored at refrigerator temperature should be noted on the package.

KRYOBULIN must not be used beyond the expiry date indicated.

Store out of the reach of children.

PACKS

KRYOBULIN

— R/C vial containing 250 i.u. of lyophilised F VIII
R/C vial containing 10 ml Water for Injections B.P.

— R/C vial containing 500 i.u. of lyophilised F VIII
R/C vial containing 20 ml Water for Injections B.P.

— R/C vial containing 1000 i.u. of lyophilised F VIII
R/C vial containing 40 ml Water for Injections B.P.

Packs contain all the equipment required for reconstitution and administration of the product.