

Enclosure No. 3

FEIBA IMMUNO - Factor Eight Inhibitor Bypassing Fraction Human
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Ad. 2.6. Contra-indications, Precautions and Warnings:

Although there has been no definite evidence of DIC attributable to the administration of FEIBA IMMUNO, it cannot be ruled out that DIC may be induced in certain cases. For this reason it is imperative that patients receiving FEIBA IMMUNO are continually examined for signs of accelerated coagulation. If an incipient DIC is suspected a platelet count and an assay of fibrinogen degradation products (FDP) should be carried out.

Treatment with FEIBA IMMUNO normalises WBCT although shortening of PTT may not take place. Thus, only WBCT - but not PTT - can be used to check on therapeutic progress.

After reconstitution with the amount of Water for Injections BP, the solution must be injected or transfused immediately by the intravenous route.