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PRODUCT LICENCE HOLDER
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Hampton Park, Eastbourne, Sussex, BN22 9AG
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FACTORATE

DATA SHEET

W0000010/1

PRESENTATION

Dried Human Antihæmophilic Fraction FACTORATE is a stable lyophilised concentrate of Factor VIII (AHF, AHG) prepared from pooled human plasma.
Each vial contains the labelled amount of antihæmophilic activity in International Units (one International Unit is the activity equivalent to the average Factor VIII content of 1 ml aliquots of 167 samples of fresh normal plasma, as determined in an international collaborative study).
Each vial also contains sufficient sodium chloride to make the reconstituted solution approximately isotonic when sterile Water for Injections B.P. is added as directed.

USES

For use in therapy of classic hæmophilia (Hæmophilia A).

DOSAGE

FACTORATE is for intravenous administration only. As a general rule one unit of Factor VIII activity per kg. will increase by 2% the circulating Factor VIII level, and although dosage must be adjusted according to the needs of the patient (weight, severity of hæmorrhage, presence of inhibitors) the following general dosages are suggested.

1. Overt bleeding

Initially 20 units per kg. of body weight followed by 10 units per kg. every eight hours for the first 24 hours and the same dose every 12 hours for the next 3 or 4 days. For massive wounds, give until bleeding stops and maintain with 20 units per kg. 8-hourly to achieve a minimum Factor VIII level of 40%.

2. Muscle Hæmorrhages

(a) Minor Hæmorrhages in extremities or non-vital areas: 10 units per kg. once a day for 2 or 3 days.
(b) Massive Hæmorrhages in non-vital areas: 10 units per kg. by infusion at 12 hour intervals for 2 days and then once a day for 2 more days.
(c) Hæmorrhages near vital organs (neck, throat, subperitoneal), 20 units per kg. initially; then 10 units per kg. every 8 hours. After 2 days the dose may be reduced by one-half.

3. Joint Hæmorrhages

10 units per kg. every 8 hours for a day; then twice daily for 1 or 2 days. If aspiration is carried out, 10 units per kg. just prior to aspiration with additional infusions of 10 units per kg. 8 hours later and again on the following day.

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4. Surgery

Dosages of 30 to 40 units per kg. body weight prior to surgery are recommended. After surgery 20 units per kg. every 8 hours should be administered. Close laboratory control to maintain the blood level of Factor VIII above 40% of normal for at least 10 days post-operatively is suggested.

5. Dental Extractions

For simple extractions a pre-operative dose of 20-25 units per kg. sufficient to raise the Factor VIII level to 50% should be given, followed by intravenous administration of epsilon aminocaproic acid. For multiple extractions further doses of Factor VIII may be advisable 24 or 36 hours after the operation.

RECOMMENDED RECONSTITUTION

Reconstitute FACTORATE using 20 ml sterile Water for Injections B.P. using standard aseptic precautions.
Warm both diluent and Factorate vials to from 20°C to 25°C. Direct diluent down the side of the vial and gently rotate the vial until contents are dissolved. DO NOT SHAKE VIAL. Vigorous shaking will cause frothing and prolong the reconstitution time. Complete solution usually takes less than 5 minutes. The solution is now ready for administration. If a gel forms on reconstitution, the preparation should not be used.

ADMINISTRATION

Standard aseptic techniques should be used at all times.

Intravenous Injection

Plastic disposable syringes are recommended with Factor VIII solution. The ground glass surfaces of all-glass syringes tend to stick with solutions of this type.
1. Attach a filter needle to a sterile disposable syringe. Insert filter needle into stopper of Factor VIII vial; inject air and withdraw the reconstituted solution from the vial.
2. Discard the filter needle and attach a suitable intravenous needle.
3. Administer solution by slow intravenous injection (20 ml in about five minutes)

Intravenous Infusion

The infusion equipment used should comply with that described in sections 3 or 4 of British Standard 2463: 1962, Transfusion Equipment for Medical Use.
1. Prepare solution of FACTORATE as recommended under Reconstitution.
2. Attach suitable infusion set.
3. If more than one vial is to be administered to the same patient the infusion set may be transferred to a second vial.
4. When infusion of FACTORATE is complete, the infusion set may be flushed with sterile isotonic saline to avoid loss of any of the reconstituted solution.
5. After use, discard infusion set, needles and vials together with any unused solution.

WARNING

Factor VIII is prepared from human plasma, each donation of which has been found negative for hepatitis B surface antigen (HB_sAg) by the radioimunoassay (RIA) method. In addition, each batch, after reconstitution as recommended, has been tested and found negative by the RIA method. However, since no completely reliable laboratory test is yet available to detect all potentially infectious plasma donations, the risk of transmitting viral hepatitis is still present.

SIDE EFFECTS

Products of this type are known to cause mild chills, nausea or stinging at the infusion site.

CONTRA-INDICATIONS

There are no known contra-indications to antihæmophilic fraction.

PRECAUTIONS

Factor VIII contains low levels of group A and B isohæmagglutinins. When large volumes are given to patients of blood groups A, B or AB, the possibility of intravascular hæmolysis should be considered. Such patients should be monitored by means of a hæmatocrit and direct Coombs test for signs of progressive anæmia.

PHARMACEUTICAL PRECAUTIONS

FACTORATE is to be stored at refrigerator temperature (2°C - 6°C). When stored as directed, it will maintain its labelled potency for the dating period indicated on the label.

LEGAL CATEGORY

P.O.M.

PACKAGE QUANTITIES

FACTORATE is supplied in single dose vials (potency is stated on each vial label.)

FURTHER INFORMATION

Hæmophilia A, a hereditary disorder of blood coagulation occurring almost exclusively in males results in profuse bleeding in joints, muscles or internal organs as a result of minor trauma. The disease appears to be due to a deficiency of a specific plasma protein, antihæmophilic factor, Factor VIII: FACTORATE provides temporary replacement of the missing clotting factor.
Affected individuals frequently require therapy following minor trauma. Surgery, when required in such individuals must be preceded by temporary correction of the clotting abnormality with fresh plasma transfusions, cryoprecipitate or by injections of Factor VIII concentrates. Obvious advantages of the use of concentrates of Factor VIII are the avoidance of hyper-proteinæmia, overloading the circulatory system and possible kidney dysfunction resulting from large volume transfusions.
Several different concentrations of Factor VIII have been used successfully. These range from Fraction I of Cohn to highly purified potent preparations. Dried Human Antihæmophilic Fraction – FACTORATE is in an intermediate category, being purified cryoglobulin complying with the standards of the B.P.