HUMAN ANTI-HAEMOPHILIC FACTOR

PRODUCT NAME:
Human Anti-Haemophilic Factor (250 IU)
Human Anti-Haemophilic Factor (500 IU)

COMPOSITION:
This product contains Factor VIII of intermediate purity, and therapeutic levels of von Willebrand's factor. It is prepared from pooled cryoprecipitate, obtained from human blood donors. Each unit in the pool has been tested and found to be non-reactive for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV) and Syphilis.

The manufacturing process includes a severe heat treatment at 80 °C for 72 hours designed to inactivate HIV, Hepatitis B and Hepatitis C Viruses.

This product is manufactured under aseptic conditions and sterility tests are carried out. The products have been prepared by a process that has been shown to yield the following on reconstitution:
- approximately 250 IU Factor VIII:C per bottle.
- approximately 500 IU Factor VIII:C per bottle.

INDICATIONS:
This product is specifically indicated for the treatment of Factor VIII deficiency (Haemophilia A). It is also of use in von Willebrand's disease.

CONTRA-INDICATIONS:
This preparation should not be used in Factor IX deficiency (Haemophilia B, Christmas disease) and does not contain therapeutic concentrations of Fibrinogen.

DOSAGE AND DIRECTIONS FOR USE:
This preparation is administered intravenously. The required dosage can be calculated from the following formula:
IU of Factor VIII required = body mass(kg) x 0,5 x desired Factor VIII increase(%)

RECONSTITUTION:
1. **Do not use if either diluent or Anti-Haemophilic Factor (AHF) bottle is cracked or if seals appear to be damaged. Do not use if any component included in the box is damaged.**
2. **Use aseptic technique throughout.**
3. Allow both the AHF and diluents to reach room temperature prior to reconstitution.
4. Remove the inner tab of the metal closure from the bottle of AHF.
5. Swab the top of the AHF bottle with sterile alcohol swab provided.
6. Unwrap the syringe and attach the needle.
7. Twist off top of Water for Injection vials (one at a time as required) and draw diluent into syringe. Repeat for all vials of diluent. Expel air from syringe with the needle in an upward position.
8. Insert the needle attached to syringe, into the centre of the stopper of the AHF bottle.
9. Inject all the diluent from the syringe at once. Mix gently.
10. Insert the airvent needle into the stopper of the AHF bottle.
11. Allow to stand at room temperature for 10-30 minutes to ensure complete protein rehydration, ie. fully reconstituted.
12. **Do not use if powder does not dissolve completely.**
13. **Use immediately after reconstitution.**
14. **Discard items used for reconstitution after use.**

ADMINISTRATION:
1. Do not administer concomitantly with other drugs.
2. Administer by slow direct **intravenous** infusion through the supplied infusion set which incorporates a filter.
3. Insert the connector of the set into the centre of the stopper. Clear tubing of air and suspend the bottle at a suitable height.
4. Insert recipient needle into patient's vein and infuse.
5. Discard any unused solution.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
As with all protein solutions, hypersensitivity reactions may occur. If symptoms such as flushing, bronchospasm, urticaria or tachycardia occur, the infusion should immediately be discontinued. For mild reactions, two 4 mg chlorpheniramine tablets taken orally are usually effective. For more severe reactions 200 mg hydrocortisone should be administered intravenously. If anaphylactic shock occurs, 0,5 ml of a 1:1 000 solution of adrenaline should be given subcutaneously. These doses must be adjusted appropriately for paediatric usage.
In the event of a reaction, stop the infusion immediately and contact the doctor and Transfusion Service.

IDENTIFICATION:
An off-white dry powder which may exhibit slight brown discolouration. On reconstituton, it forms a lightly coloured, opalescent solution which may exhibit slight flocculation.

PRESENTATION:
Lyophilised powder in a clear glass infusion bottle with rubber stopper and metal closure. Items for reconstitution and infusion are supplied.

STORAGE INSTRUCTIONS:
Prolonged storage: 2 °C - 10 °C.
Short term storage and transport: Room temperature.
Do not expose to direct sunlight.
Keep out of reach of chidren.

MANUFACTURER:
WESTERN PROVINCE BLOOD TRANSFUSION SERVICE (WPBTS)
101 - 103 Connaught Road
Beaconvale
PAROW
7500
Tel: +27 (21) 933-9400 or 507-6300
Fax: +27 (21) 931-5551 or 531-0322
BLOOD PROCESSING LICENCE NUMBER P1
08/08 16103

MENSLIKE ANTI-HEMOFILIESE FAKTOR

PRODUKNAAM:
Menslike Anti-Hemofiliese Faktor (250 IE)
Menslike Anti-Hemofiliese Faktor (500 IE)

SAMESTELLING:
Hierdie produk bevat ´n intermediêr gesuiwerde Faktor VIII-preparaat en terapeutiese vlakke van von Willebrand se faktor. Dit word uit saamgevoegde kriopresipitaat, afkomstig van menslike bloedskenk -ers, voorberei. Elke eenheid in die samevoeging is onreaktief bevind vir Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Menslike Immuniteitsgebrek virus (MIV) en Syphilis.

Die vervaardigingsproses sluit ´n streng verhittingstap vir 72 uur teen 80 °C in, wat daarop gemik is om MIV-, Hepatitis B- en Hepatitis C-virusse te onaktiveer.

Hierdie produk word onder aseptiese toestande vervaardig en steriliteitstoetse word gedoen. Die produkte is vervaardig deur ´n proses wat die volgende samestelling na hersamestelling toon:
- ongeveer 250 IE Faktor VIII per bottel.
- ongeveer 500 IE Faktor VIII per bottel.

INDIKASIES:
Hierdie produk word spesifiek aangedui vir die behandeling van Faktor VIII-gebrek (Hemofilie A). Dit is ook nuttig vir die behandeling van von Willebrand se siekte.

KONTRA-INDIKASIES:
Hierdie preparaat mag nie vir Faktor IX-gebrek (Hemofilie B, Kersfees-siekte) gebruik word nie en bevat ook nie terapeutiese konsentrasies fibrinogeen nie.

DOSERING EN GEBRUIKSAANWYSINGS:
Hierdie preparaat word binneaars toegedien. Die vereiste dosis kan deur middel van die volgende formule bereken word:
IE Faktor VIII vereis = liggaamsmassa (kg) x 0,5 x gewenste Faktor VIII-toename(%)

HERSAMESTELLING:
1. **Moenie gebruik indien Anti-Hemofiliese Faktor (AHF) of oplosmiddel bottel gekraak is, of as dit blyk dat die seëls beskadig is nie. Moenie gebruik as enige van die items in die karton beskadig is nie.**
2. **Gebruik deurentyd aseptiese tegniek.**
3. Die AHF en die oplosmiddel, net voor hersamestelling , moet by kamer temperatuur wees.
4. Verwyder die binneste deel van die metaalsluiting van die AHF bottel.
5. Vee die prop van die AHF bottel met die ingeslote steriel pluisie.
6. Maak die spuit oop en heg die naald daaraan.
7. Draai die boonste gedeelte van die oplosmiddel buisie af en suig die oplosmiddel met die spuit en naalde op. Herhaal met die ander buisies. Pers die lug uit die spuit met die naald na bo gehou.
8. Steek die inspuitnaald in die middel van die prop in die AHF bottel in.
9. Spuit al die oplosmiddel terselfdetyd in die bottel in. Draai die bottel sagkens in die rondte om die AHF op te los.
10. Druk die ontlugter naald in die AHF bottel se prop.
11. Laat die bottel vir 10-30 minute teen kamertemperatuur staan om volledige rehidrasie van die proteiene te verseker, dit is, volledig hersaamgestel.
12. **Moenie die produk gebruik as die poeier nie volledig oplos of as daar ´n jel by hersamestelling vorm nie.**
13. **Gebruik onmiddellik na hersamestelling.**
14. **Gooi die items wat gebruik vir die hersamestelling is, na gebruik weg.**

TOEDIENING:
1. Moenie gelyktydig met ander dwelmmiddels toedien nie.
2. Dien die oplossing deur stadige direkte **binneaarse** infusie toe via die ingeslote toedieningstel, wat ´n filter insluit.
3. Steek die verbinder van die toedieningstel deur die middel van die prop. Verwyder enige lug uit die buis en hang die bottel teen ´n geskikte hoogte op.
4. Plaas die ontvangernaald in die pasiënt se aar en spuit in.
5. Gooi enige ongebruikte oplossing weg.

NEWE-EFFEKTE EN SPESIALE VOORSORG MAATREËLS:
Soos met alle proteienoplossings, kan hipersensitiwiteit voorkom. Indien simptome soos verhoogde gelaatskleur, brongospasme, urtikarie of tagidardie voorkom, moet die infusie onmiddellik gestaak word. In die geval van ´n matige reaksie is mondelike toediening van twee 4 mg chloorfeniramien tablette gewoonlik doeltreffend. Vir meer ernstige reaksies moet 200 mg hidrokortisoon binneaars toegedien word. As anafilaktiese skok voorkom, moet 0,5 ml van ´n 1:1000 oplossing van adrenalien subkutaan toegedien word. Hierdie dosis moet toepaslik aangepas word vir pediatriese behandeling.
In geval van ‘n reaksie, staak die oortapping onmiddellik en stel die dokter en oortappingsdiens in kennis.

IDENTIFIKASIE:
´n Amperwit, droë poeier wat effens bruin mag vertoon. By hersamestelling vorm ´n liggekleurde, opaalagtige oplossing wat geringe flokkulasie kan vertoon.

AANBIEDING:
Droog bevrore poeier in ´n helder glasinfusiebottel met ´n rubberprop en metaalsluiting.
Items vir hersamestelling en oortapping is verskaf.

BERGINGSAANWYSINGS:
Langtermynberging: 2 °C - 10 °C.
Kort-termynberging en vervoer: Kamertemperatuur.
Moenie aan direkte sonlig blootstel nie.
Hou buite bereik van kinders.

VERVAARDIGER:
WESTELIKE PROVINSIE BLOEDOORTAPPINGS DIENS (WPBOD)
Connaughtweg 101-103
Beaconvale
PAROW
7500
Tel: +27 (21) 933-9400 of 507-6300
Faks: +27 (21) 931-5551 of 531-0322
BLOEDVERWERKINGSLISENSIENOMMER P1
08/08 16103