HANDELSNAAM: WPBT - 20% Albumin 50 ml
WPBT - 20% Albumin 100 ml

BESKRYWENDE NAAM: Mensserumalbumien - 20% Proteïenoplossing.

REGISTRASIENOMMER:
50 ml - T706 (Wet 101/1965 soos wysiging)
100 ml - T707 (Wet 101/1965 soos wysiging)

FARMAKOLOGIESE KLASSIFIDASIE: Kategorie A.30.3 Bloedfraksies.

SKEDULERINGSTATUS: S4

SAMESTELLING:
Die oplossing het die volgende samestelling:

Totale Proteïene	200 g/l
Albumien	≥ 96% van Totale Proteïen
Natrium	≤ 130 mmol/l
Kalium	≤ 10 mmol/l
Osmolaiteit	220 mOsm/kg
pH	7,0

Bevat geen preserveermiddel nie.
Gestabiliseer met Natriumkaprielaat.

Elke afsonderlike eenheid plasma in die poel is onreaktief bevind vir Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Menslike Immuniteitsgebrek Virus (MIV) en Syphilis. Die vervaardigingsproses sluit ook pasteurisasie vir 10 uur teen 60 °C in.

IDENTIFIKASIE: 'n Helder geel tot oranje-bruin vloeistof.

FARMAKOLOGIESE WERKING:
Albumien is verantwoordelik vir 80% van die kolloïede onkotiese druk van die plasma.
Albumien dien as 'n draer proteïen vir verskeie hormone, vetsure, metaboliete (bv. Bilirubien) en geneesmiddels.

INDIKASIES:
Ter aanvulling van bloedvolume in pasiënte met skok.
Behandeling van proteïenverlies in pasiënte met veelvuldige brandwonde.
As 'n aanvulling by pasiënte wat dialise ondergaan.
Geleentheidsgebruik in vervangingsterapie in pre- en post-operatiewe hipoproteïenemie, akute lewerversaking en akute refrose en respiratoriese benoudheidssindroom by volwassenes asook 'n vervangingsoplossing na terapeutiese plasmaferese.

KONTRA-INDIKASIES:
Gekonsentreerde oplossings van albumien is teenaangedui in akute anemie en hartversaking.
Hierdie produk is nie geskik vir gebruik in vroeggebore babas nie.

DOSIS EN GEBRUIKSAANWYSINGS:

A. VIR AKUTE HIPOVOLEMIE EN IN DIALISE PASIËNTE
In bogenoemde toestand moet albumien in 'n 5% oplossing toegedien word, wat voorberei kan word deur 1 volume van hierdie produk by 3 volumes van 'n gepaste kristalloïede oplossing by te voeg.

B. VERVANGINGSTERAPIE
Die aantal gram albumien benodig, kan volgens die volgende formule bereken word:
(Verlangde albumienvlak - eintlike albumienvlak) X Plasma volume X 2.

$$\left[\text{Plasma volume in liter} = \frac{\text{Pasiënt se gewig in kg X 40}}{1000}\right]$$

C. TOEDIENINGSTEMPO
1 ml albumienoplossing per minuut.
'n Sirkulasie-oormaat mag gedurende die infusie van hierdie produk voorkom. Versigtige berekening van die hoeveelheid, infusietempo en gereelde kliniese evaluering gedurende toediening is nodig.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Hierdie produk is 'n stabiele plasmaproteïenoplossing, en die binneaarse gebruik daarvan veroorsaak selde rampspoedige reaksies. Allergiese reaksies is al aangemeld.

Wanneer binneaars toegedien, sal elke volume van hierdie oplossing binne 15 minute ongeveer 3 ½ volumes bykomende vloeistof in die sirkulasie bewerkstellig.

In pasiënte met intrinsieke hartsiekte en 'n verlaagde kardiale reserwe, bestaan daar die risiko van pulmonêre edeem met die toediening van 'n hipertoniese albumienoplossing as gevolg van die styging in die intravaskulêre volume.

WAARSKUWINGS:
Hierdie oplossing is 'n bloedprodukt en die gebruik daarvan kan lei tot 'n oortappingsreaksie.
In die geval van 'n oortappingsreaksie, staak die oortapping onmiddellik en kontak die dokter in bevel van die pasiënt.
Stel die Oortapingsdiens onmiddellik in kennis.

In die geval van dood is die verslag aan die Oortappingsdiens bykomend die normale verslae in verband met onnatuurlike doodsoorsaak.

BEKENDE SIMPTOME VAN OORDOSERING EN DIE BEHANDELING DAARVAN:
Die enigste beduidende komplikasie van oordosering is die moontlike ontwikkeling van pulmonêre edeem, te wyte aan vinnige styging van die plasmavolume in 'n pasiënt met verminderdekardiale reserwes. Die pasiënt moet dienooreenkomstig dopgehou word vir die skielike aanvang van dispnee met gepaardgaande rusteloosheid, sianose en die ekspektorasie van skuimerige sputum.

Behandeling:
Staak die oortapping van Albumien en pas behandeling soos vir ander oorsake van pulmonêre edeem toe, bv. regopposisie en die toediening van morfien, amminofillien, diuretika, suurstof ens.

AANBIEDING:
Oplossing van 50 ml of 100 ml in 'n helder glas-toedieningsbottel met 'n rubberprop en 'n metaal-riffeldop.

BERGINGSVOORSKRIFTE:
Bewaar teen 2 °C to 25 °C maar verkieslik in 'n koelkas teen 4 °C. Beskerm teen lig. Die oplossing moet onmiddellik gebruik word nadat die bottel oopgemaak is om die risiko van mikrobiologiese besmetting te verminder.
Hou buite bereik van kinders.

NAAM VAN APPLIKANT:
Westelike Provinsie Bloedoortappingsdiens
Connaughtweg 101
Beaconvale
Parow
7500
Tel: +27 (21) 933-9400 / 507-6300
Faks: +27 (21) 931-5551 / 531-0322

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
08/08 16021

PROPRIETARY NAME: WPBT - 20% Albumin 50 ml
WPBT - 20% Albumin 100 ml

DESCRIPTIVE NAME: Human Serum Albumin - 20% Protein Solution.

REGISTRATION NUMBER:
50 ml - T706 (Act 101/1965 as amended)
100 ml - T707 (Act 101/1965 as amended)

PHARMACOLOGICAL CLASSIFICATION: Category A.30.3 Blood Fractions

SCHEDULING STATUS: S4

COMPOSITION:
This solution has the following composition:

Total Protein	200 g/l
Albumin	≥ 96% of Total Protein
Sodium	≤ 130 mmol/l
Potassium	≤ 10 mmol/l
Osmolality	220 mOsm/kg
pH	7,0

Contains no preservative.
Stabilised with Sodium Caprylate.

Each individual unit of plasma in the pool is non-reactive for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV) and Syphilis. The manufacturing process also includes pasteurisation for 10 hours at 60 °C.

IDENTIFICATION: A clear amber to deep orange-brown liquid.

PHARMACOLOGICAL ACTION:
Albumin is responsible for 80% of the colloid oncotic pressure of the plasma.
Albumin acts as a carrier protein for various hormones, fatty acids, metabolites (eg. Bilirubin) and drugs.

INDICATIONS:
Expansion of blood volume in patients with shock.
Treatment of protein loss in patients with extensive burns. As an adjunct to exchange transfusion in fullterm neonates with hyperbilirubinaemia. As an adjunct in patients undergoing dialysis.
Occasional use in replacement therapy in pre- and post-operative hypoproteinaemia, acute liver failure and acute nephrosis and adult respiratory distress syndrome and as a replacement fluid during therapeutic plasmapheresis.

CONTRA-INDICATIONS:
Concentrated solutions of albumin are contra-indicated in severe anaemia and heart failure.
This product is not suitable for use in premature infants.

DOSAGE AND DIRECTIONS FOR USE:

A. FOR ACUTE HYPOVOLAEMIA AND IN DIALYSIS PATIENTS
In the above condition albumin should be given in 5% solution, which can be prepared by adding 1 volume of this product to 3 volumes of appropriate crystalliod solution.

B. REPLACEMENT THERAPY
The number of grams of albumin required can be calculated from the following formula:
(Desired albumin level - actual albumin level) X Plasma volume X 2.

$$\left[\text{Plasma volume in litres} = \frac{\text{Patient's weight in kg X 40}}{1\,000}\right]$$

C. RATE OF ADMINISTRATION
1 ml albumin solution per minute.

Circulatory overload may occur during infusion of this product. Careful calculation of the amount and rate of infusion and frequent clinical assessments during administation are necessary.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
This product is a stable plasma protein solution and its intravenous use seldom causes untoward reactions. Occasional allergic reactions have been reported.

When infused intravenously each volume of this solution will draw about 3 ½ volumes of additional fluid into the circulation within 15 minutes.

In patients with intrinsic heart disease and lowered cardiac reserve there is the risk of pulmonary oedema with the administration of hypertonic albumin solution as a result of the rise in intravascular volume.

WARNINGS:
This solution is a blood product and its use can result in a transfusion reaction.
In the event of a transfusion reaction, stop the transfusion at once and contact the doctor in charge of the patient.
Report to the Transfusion Service promptly.

In the event of a fatality, the report to the Transfusion Service is additional to the usual reports in connection with death from unnatural causes.

KNOWN SYMPTOMS OF OVERDOSAGE AND THEIR TREATMENT:
The only significant complication of overdosage is the possible development of pulmonary oedema, due to rapid increase of the plasma volume in a patient with diminished cardiac reserve. Accordingly the patient should be observed for the sudden onset of dyspnoea, accompanied by restlessness, cyanosis and the expectoration of frothy sputum.

Treatment:
Stop the infusion and institute treatment as for other causes of pulmonary oedema which would include an upright position and administration of morphine, aminophylline, diuretics, oxygen, etc.

PRESENTATION:
50 ml or 100 ml of solution in a clear glass infusion bottle with rubber stopper and metal crimp cap.

STORAGE DIRECTIONS:
Store at 2 °C to 25 °C but preferably in a refrigerator at 4 °C.
Protect from light. This solution should be used immediately to minimise the risk of microbiological contamination.
Keep out of reach of children.

NAME OF APPLICANT:
Western Province Blood Transfusion Service
101 Connaught Road
Beaconvale
Parow
7500
Tel: +27 (21) 933-9400 / 507-6300
Fax: +27 (21) 931-5551 / 531-0322

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
08/08 16021