SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Mannitol 10% solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mannitol BP for Injections 10% w/v

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For use as an osmotic diuretic alone or to supplement the action of other diuretics in order to promote renal function, including the assisted elimination of drugs such as aspirin and barbiturates.

4.2 Posology and method of administration

Posology

Adults and Children

The volume, strength and rate of infusion of mannitol solutions given in intravenous will depend upon the requirements of the patient and the judgement of the physician.

A dosage of 200 g daily by intravenous infusion should not be exceeded.

Elderly

Elderly patients are more susceptible to the adverse effects associated with mannitol. This is due to diminished renal and cardiac reserves. Elderly patients should therefore be given a test dose as described below for patients with renal impairment.

Renal Impairment

Patients with impaired renal function should be given a test dose of 200 mg per kilogram body weight administered over five minutes and if 40 ml or more of urine is produced in an hour, mannitol may then be given in therapeutic doses.

Method of administration

Intravenous use.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

Mannitol is contraindicated in, patients with abnormal capillary fragility, pulmonary congestion or pulmonary oedema, intracranial bleeding, congestive heart failure and renal failure unless a test dose has produced a diuretic response.

4.4 Special warnings and precautions for use

Solutions of mannitol given in intravenous infusion should be administered slowly and should not be mixed with blood in transfusion apparatus. All patients given mannitol should be observed for signs of fluid and electrolyte imbalance.

If renal flow is inadequate, water intoxication is likely in patients receiving intravenous mannitol, therefore its use in oedematous conditions associated with diminished cardiac reserve should only be considered if the advantages outweigh the risks.

The label states:

To retard crystallisation store at 20°- 30°.

Carefully examine the solution for crystals immediately before use.

If necessary redissolve by raising the temperature to 60°, maintaining it at this temperature, and shaking occasionally until the crystals have redissolved.

Cool to blood heat before use.

4.5 Interaction with other medicinal products and other forms of interaction

Mannitol may enhance tubocurarine-induced neuromuscular blockade. Cyclosporin nephrotoxicity may be enhanced by the concurrent administration of mannitol.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of mannitol infusion has not been established in pregnancy and it should be used with caution.

Breast-feeding

The safety in lactation has not been assessed but its use in this period is not considered to constitute a hazard.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Rapid intravenous infusion of mannitol may produce headache, chills or chest pain. It may also depress respiration by altering the acid base and electrolyte balance of the body fluids.

Convulsions have been known in, patients administered excessive doses of mannitol solutions.

Other side effects reported may be associated with hypersensitivity reactions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows the continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9. Overdose

Treatment of overdo sage with mannitol should be symptomatic and, in particular, directed at correction of fluid and electrolyte imbalance.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mannitol is an osmotically active solute, which is filtered at the glomerulus, and produces a corresponding increase in urine volume.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

Hydrochloric acid

Sodium Hydroxide

6.2. Incompatibilities

Mannitol should not be mixed with blood because of possible agglutination and irreversible crenation.
Electrolyte solutions should not be added to mannitol infusions, since addition is likely to salt out the mannitol.
Other drugs which are incompatible with mannitol solutions include; corticotrophin, soluble barbiturates, noradrennaline, metaraminol, suxamethonium and tetracyclines.

6.3 Shelf life

500ml Polyethylene container – 60 months

500ml polyolefin bags – 36 months

6.4 Special precautions for storage

Store between 20° - 30°C

6.5 Nature and contents of container

Sealed semi-rigid, cylindrical neutral polythene 500ml container with a 'Twist-off' seal at one end and a ring tab at the opposite end

Or

A flexible 500ml polyolefine bag sealed in a polyolefine overwrap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Polyfusor:

Do not dilute before use.

Use standard sterile peritoneal dialysis equipment.

free*flex*:

Locate the corner tabs at the end of the bag. Grip the two tabs and pull the two halves of the overwrap apart, releasing the bag onto a clean surface.

<u>Setting up the solution:</u>

Position the roller clamp of the giving-set to just below the drip chamber and close.

Hold the base of the giving set port firmly and grip the wings of the twist of tab. Twist to remove the protective cover. Still holding the base of the giving-set port push the set spike fully into the port to ensure a leak proof connection. Prime the set in accordance with the manufacturer's instructions.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0033

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10th May 1989 / 16th January1995

10 DATE OF REVISION OF THE TEXT

06/11/2014