Mannitol 20% w/v Intravenous Infusion BP

Pharmaceutical form
Solution for infusion
Clear, colourless aqueous solution

Composition
1000 ml of solution contain
Active ingredients:

Mannitol	200.0 g

Excipients:
Water for Injections

Physico-chemical characteristics:

Theoretical osmolarity	1100 mOsm/l
Titration acidity (to pH 7.4)	< 0.2 mmol/l
pH	4.5 - 7.0

Indications
- Prevention of acute renal failure (after positive response to test infusion);
- Reduction of intracranial pressure;
- Forced diuresis to promote the urinary excretion of toxic substances;
- Supportive systemic therapy of acute glaucoma

Contraindications
Mannitol solutions must not be given in cases of
- Persistent oligo- or anuria after test infusion;
- Acute cardiac decompensation;
- Lung oedema;
- Dehydration;
- Hyperosmolality of the serum, i. e. > 320 mOsm/kg,
- Intracranial bleeding;
- Obstructions in the urinary tract.

Special warnings and precautions for use
Special warnings
This solution is only indicated for osmotherapy .The solution should be administered with caution in cases of hypervolaemia.
In cases of oligo- or anuria, osmotherapy with mannitol solutions should only be performed after a successful test infusion.

Precautions for use
The patient's cardiovascular status should be carefully assessed before starting osmotherapy and should be monitored during therapy.
Sufficient hydration of the patient should be ensured before beginning of osmotic diuresis. Dehydration should therefore be corrected before start of therapy.
Clinical monitoring during osmotherapy should include checks of water, electrolyte and acid-base balance, serum osmolarity, renal function, heart function and blood pressure.
The efficacy of all osmotherapeutic agents decreases after repeat therapy.
For monitoring of the urine excretion use of a closed collecting system is recommended.
Mannitol solutions must not be infused through the same infusion line simultaneously with, before, or after the transfusion of blood because of the danger of pseudo-agglutination.

Pregnancy and Lactation
Pregnancy
Mannitol passes the placental barrier.
For mannitol solutions for osmotherapy no controlled clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development, and clinical reports such effects are not known so far.
Yet caution should be exercised when administering mannitol solutions to pregnant women and the doses should be chosen as low as possible.

Lactation
It is not known whether mannitol is secreted into breast-milk. Therefore the solutions should be administered to nursing women with due caution.

Undesirable effects
Depending on the dose and the patient's clinical condition, electrolyte and fluid imbalances with hyper- or hyponatraemia, hyper- or hypokalaemia, and hyper- or dehydration may occur. At the beginning of osmotherapy with mannitol infusions and in particular in cases of overdose, excess fluid administration and dilution of serum electrolytes may result in hyponatraemia and consecutively, hyperkalaemia.
Polyuria following longer lasting administration of mannitol solutions may lead to increased water loss, resulting in hypernatraemia and consecutively, hypokalaemia.
In the presence of very high mannitol concentrations in the plasma or in acidosis, mannitol can cross the blood-brain barrier producing a rebound increase in the intracranial pressure.
Blood and the lymphatic system disorders
Water and electrolyte imbalances, see above.
Immune system disorders
Very rare: Hypersensitivity reactions, either local reactions such as rhinitis, urticaria, rash, or systemic anaphylactic reactions like fever, oedema, respiratory distress, hypotension, tachycardia or anaphylactic shock.

Metabolism and nutrition disorders
Rare: Acidosis.

Nervous system disorders
Rare: Headache, dizziness.

Eye disorders
Rare: Blurred vision.

Gastrointestinal disorders
Rare: Dryness of mouth, nausea, vomiting, upper abdominal trouble.

Musculoskeletal, connective tissue and bone disorders
Rare: Transient muscle rigidity.

General disorders and administration site conditions
Rare: Chills, fever, arm pain, backache, angina-like chest pain;
Irritation of the veins and phlebitis after infusion into small veins.

Store at 20°C to 30°C.

Marketing authorization holder:
B. Braun Melsungen AG, Carl-Braun-Str. 1, D-34212 Melsungen

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