135+166/12627934/0420

Directions for use
Read carefully!

B. Braun Osmofundin® 10%
B. Braun Osmofundin® 20%

Solutions for osmotherapy

Composition

Each 100 ml contains:

	B. Braun Osmofundin® 10%	B. Braun Osmofundin® 20%
Mannitol	10.0 g	17.5 g
Sorbitol for Parenteral Use	-	2.5 g
Sodium Chloride	0.26 g	-
Sodium Acetate .3H_2O	0.34 g	-
Water for Injections to	100 ml	100 ml
Electrolytes:	mmol/l	
Na^+	70	
Cl^-	45	
$Acetate^-$	25	
Osmolarity:	690 mOsm/l	1100 mOsm/l

Characteristics

B. Braun Osmofundin® contains mannitol, a hexavalent sugar alcohol which is not metabolised but eliminated via the kidneys together with a corresponding amount of water. Thus mannitol promotes urine excretion by means of osmotic diuresis and also improves renal blood flow. For galenic reasons 2.5% sorbitol has been added to B. Braun Osmofundin® 20%.

Indications

Prophylaxis of acute renal failure
Postoperative oliguria
In forced diuresis for eliminating toxic substances via the kidneys
For decreasing intracranial pressure in case of cerebral oedema
Prior to cataract operations
Therapy-resistant oedema
For the B. Braun Osmofundin® test to determine renal function

B. Braun Osmofundin® test:

100 ml of B. Braun Osmofundin® 20% or 200 ml of B. Braun Osmofundin® 10% are infused within 15 minutes. If the urine excretion, which can be accurately measured with the urimeter Ureofix®, remains below 30-40 ml/h, then this may be indicative of an organic renal damage. If, on the contrary, the urine excretion exceeds 40 ml/h, then the osmotherapy with B. Braun Osmofundin® can be continued, whereby a diuresis rate of 100 ml/h should be finally aimed at.

Dosage

Unless otherwise prescribed:
B. Braun Osmofundin® 10%
500-1000 ml per day corresponding to 50-100 g mannitol
B. Braun Osmofundin® 20%
250-500 ml per day corresponding to 50-100 g of polyols (= mannitol + sorbitol)
Drop rate: 30-60 drops/min. ≙ 90-180 ml/h
The above total dose of 100 g mannitol in 24 hours should only be exceeded if at least 100 ml/h of urine are excreted.

Route of administration I.V.

Side effects

Osmotherapy may involve enhanced renal fluid and electrolyte losses accompanied by circulatory disturbances.
The necessary amount of fluid is to be replaced according to the actual status of the circulation, for which purpose electrolyte solutions, plasma

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Dokument = 148 x 210 mm (DIN A5)
2 Seiten

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Osmofundin® 10%
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volume replacement fluids like Gelafundin®/ Onkovertin®, or carbohydrate solutions may be used. During osmotherapy the electrolyte status requires close observation. Should the patient complain of nausea, headache etc., the drop rate should be reduced.

Contraindications

B. Braun Osmofundin® is contraindicated in case of:
Dehydration,
Manifest cardiac insufficiency,
Continued oligo-anuria after B. Braun Osmofundin® test,
Fructose-sorbitol-intolerance (only for B. Braun Osmofundin® 20%),
Fructose-1, 6-diphosphatase deficiency.

Warning

If a hereditary fructose-sorbitol intolerance (see contraindications - 'fructose-sorbitol intolerance') is not recognized, the administration of sorbitol-containing infusion solutions may lead to nausea, hypoglycaemia, increase in lactate, acidosis and acute liver damage with the possibility of lethal outcome. Therefore a fructosesorbitol intolerance must be excluded prior to starting the infusion of sorbitol-containing solutions. For this purpose the patient or relatives shall be asked about the symptoms of fructose intolerance (nausea and signs of hypoglycaemia after the ingestion of fruits). In unconscious patients or in cases, where the possibilities for anamnesis are insufficient, sorbitol-containing solutions should not be administered.

If in these patients an indication for the application of this substrate exists because of a pathological disturbance of metabolism (e.g diabetes mellitus or posttraumatic stress), the administration should be performed under close metabolic supervision, looking specially for the typical hypoglycaemia.

Precautions

The compatibility of any additives to this solution should be checked before use.

Before commencing the therapy with B. Braun Osmofundin® it must be ensured that the patient does not suffer from dehydration which otherwise needs to be treated first. B. Braun Osmofundin® is, because of its hypertonic nature, to be infused strictly intravenously as otherwise tissue necrosis may develop. When stored below normal room temperature (+20°C), B. Braun Osmofundin® 20% may form mannitol crystals which, however, quickly disappear by warming the container in warm water. As an additional safety measure the infusion set used for administration should be fitted with an integral fluid filter.

Symptoms and treatment of overdosage

Fluid and electrolyte imbalance should be treated accordingly. If symptoms like nausea, headache, etc occur, the drop rate should be reduced.

Usage during pregnancy

No adverse reaction has been reported.

Shelf life

The product must not be used beyond the expiry date stated on the label.

Storage

The product should not be stored above the temperature stated on the label.

Presentation

B. Braun Osmofundin® 10%, 20% 250 ml, 500 ml plastic container (with and without infusion set)

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Product registration holder and manufactured by:
B. Braun Medical Industries Sdn. Bhd.
11900 Bayan Lepas,
Penang, Malaysia.