

## **ABTOL , Mannitol Intravenous Infusion 20% w/v**

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

### **In this leaflet:**

- a) What ABTOL is and what it is used for
- b) Before you use ABTOL
- c) How to use ABTOL
- d) Possible side effects
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#### **a) What ABTOL is and what it is used for**

ABTOL is an intravenous infusion which is indicated for use as an osmotic diuretic in the following situations:

- Promotion of diuresis in the prevention and/or treatment of the oliguric phase of acute renal failure before irreversible renal failure becomes established.
- Reduction of intracranial pressure and cerebral oedema, when blood-barrier is intact.
- Reduction of elevated intraocular pressure when it cannot be lowered by other means.
- Promotion of elimination of renally excreted toxic substances in poisoning:

ABTOL contains the active ingredient Mannitol.

#### **b) Before you use ABTOL**

**DO NOT** use ABTOL if you are allergic to any of the ingredients.

#### **Take special care**

Mannitol should not be administered in patients with hypovolemic shock or renal dysfunction until volume and electrolytes have been restored.

Mannitol should not be given concomitantly with blood because it may cause agglutination and crenation of blood cells.

When exposed to low temperatures, solutions of mannitol may crystallize. Inspect for crystals prior to administration. If crystals are visible, redissolve by warming the solution up to 70°C, with agitation.

**ENSURE THAT THE SOLUTION IS COOLED TO 37° C BEFORE INFUSION**

Before use, ensure that the container is undamaged and the contents clear in appearance. After use, discard any remaining solution.

### **Pregnancy and breast feeding**

Mannitol should not be used during pregnancy and when breast feeding unless clearly needed.

### **Effects on ability to drive and use machines**

ABTOL has no effect on the ability to drive and use machine

## **c) How to use ABTOL**

### Dosage

The choice of the specific mannitol concentration, dosage and rate of administration depends on the age, weight, clinical and biological condition of the patient and concomitant therapy.

### Method of administration

ABTOL should be administered via a large peripheral or preferably a central vein. Rapid infusion in peripheral veins may be harmful.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use only if the solution is clear, without visible particles and the seal is intact.

**If you get any side effects**, talk to your doctor, pharmacist or healthcare provider. This includes any possible side effects not listed in this leaflet.

## **d) Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experience any of the following side effects, you should tell your doctor immediately. These are symptoms of an allergic reaction.

<b>System or Organ Class</b>	<b>Adverse Drug Reaction</b>
Immune System disorder	Allergic reaction Anaphylactic reaction including anaphylactic shock
Metabolism and Nutritional disorders	Fluid and Electrolyte imbalance - Dehydration - Oedema - Metabolic acidosis
Nervous system disorders	Headache

	Dizziness Rebound intracranial pressure increase CNS toxicity manifested by: <ul style="list-style-type: none"> <li>- Convulsions</li> <li>- Coma</li> <li>- Confusion</li> <li>- Lethargy</li> </ul>
Eye disorder	Blurred vision
Cardiac disorders	Cardiac arrhythmia Congestive heart failure
Vascular disorders	Hypotension Pulmonary oedema
Respiratory, thoracic and mediastinal disorders	Rhinitis
Gastrointestinal disorders	Mouth dry
Skin and subcutaneous tissue disorders	Skin necrosis Urticaria
Musculoskeletal and connective tissue disorders	Cramps
Renal and urinary disorders	Excessive diuresis Nephrosis osmotic Urinary retention Acute renal failure Azotemia Anuria Oliguria Polyuria
General disorders and administration site conditions	Chills Chest pain (angina-like chest pain) Fever Asthenia Malaise Infusion site reactions including: <ul style="list-style-type: none"> <li>- infusion thrombophlebitis</li> <li>- infusion site inflammation</li> <li>- infusion site pain</li> <li>- infusion site rash</li> <li>- infusion site erythema</li> <li>- infusion site pruritus</li> </ul> Compartment syndrome (associated with extravasation and swelling at the injection site)

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. Reporting of side effects If you get any side effects, talk to your doctor or pharmacist.

**e) How to store ABTOL**

Keep out of reach of children.

Store below 30°C, but do not freeze.

Do not use after the expiry date which is stated on the bottle after “Expiry”. The expiry date refers to the last day of that month.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**f) Further information**

**What ABTOL contains**

The **active** ingredient is Mannitol (20% w/v).

The **other** ingredient is water.

**What ABTOL looks like and the contents of the pack**

ABTOL is clear, colorless or almost colorless solution packed in 100mL plastic bottles.

**Marketing authorization holder and manufacturer**

Abacus Parenteral Drugs Limited

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