SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hartmann's Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Polyfusor H has the following composition:

Name	%w/v
Sodium Chloride BP for Injections	0.6
Potassium Chloride BP	0.04
Calcium Chloride BP Dihydrate	0.027
Sodium Hydroxide BP	
Lactic Acid BP	
Lactic Acid BP and Sodium Hydroxide BP are added as 2M or premade 50% Sodium Lactate Solution equivalent to Sodium Lactate	0.317

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intravenous infusion

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hartmann's solution is indicated for the treatment of metabolic acidosis and dehydration with acidosis. It may be used to expand extracellular fluids or restore extracellular electrolyte. It may be used in the treatment of diabetic coma.

For intravenous infusion.

4.2 Posology and method of administration

Adults and Children

The infusion rate and volume depend on the age, weight, clinical condition (e.g. burns, surgery, head-injury, infections), and concomitant therapy should be determined by the consulting physician experienced in paediatric intravenous fluid therapy (see sections 4.4. and 4.8).

A dosage of 300 ml per hour should not be exceeded.

Elderly

Care should be taken in the elderly to avoid circulatory overload, particularly in, patients with cardiac and renal insufficiency.

Fluid balance, serum electrolytes and acid-base balance may need to be monitored before and during administration, with particular attention to serum sodium in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs, due to the risk of hospital acquired hyponatraemia (see sections 4.4, 4.5 and 4.8).

Monitoring of serum sodium is particularly important for hypotonic fluids.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

Patients with sodium overload. This may occur with myocardial and renal damage but also in the first five or six days after surgery or severe trauma when there may be an inability to excrete unwanted sodium. Hartmann's solution should not be given to patients with cardiac arrhythmias. Lactate containing solutions are contraindicated in, patients with severe liver disease who are unable to convert lactate to bicarbonate.

4.4 Special warnings and precautions for use

Although Hartmann's solution provides potassium, this is only enough to maintain the potassium content of extracellular fluid and would be quite inadequate for patients with severe potassium loss. Under these circumstances potassium supplements must be given. Lactate overdose in, patients with heart disease may provoke arrhythmias and heart failure. ECG monitoring is recommended if Hartmann's solution is administered to such patients use with caution in, patients with cardiac failure, hypertension, impaired renal function, peripheral and pulmonary oedema and in toxaemia of pregnancy.

The label states: Do not use unless the solution is clear and free from particles.

High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatraemia (see below).

Hyponatraemia
Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and

kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with cerebral oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, cerebral contusion and brain oedema) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs leading to an increased vasopressin effect
The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.2, 4.4 and 4.8).

- Drugs stimulating vasopressin release include:
  Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action include:
  Chlorpropamide, NSAIDs, cyclophosphamide
- Vasopressin analogues include:
  Desmopressin, oxytocin, vasopressin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

4.6 Fertility, pregnancy and lactation

Hartmann's solution should be administrated with special caution for pregnant women during labour particularly as to serum-sodium if administered in combination with oxytocin (see section 4.4, 4.5 and 4.8).

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

- Thrombosis of the chosen vein is always possible with intravenous infusion.
- Hospital acquired hyponatraemia*
- Acute hyponatraemic encephalopathy*

*Hospital acquired hyponatraemia may cause irreversible brain injury and death, due to development of acute hyponatraemic encephalopathy, frequency unknown (see sections 4.2. 4.4, 4.5).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdosage may lead to fluid overload and electrolyte imbalance. The use of diuretic may be indicated for the treatment of fluid and electrolyte disturbance.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Electrolytes, ATC code: B05BB01

Potassium chloride, sodium chloride and calcium chloride provide essential ions to maintain the intracellular/extracellular milieu.

Sodium lactate is used as a source of bicarbonate ions, which will correct acid-base balance.

5.2 Pharmacokinetic properties

Sodium lactate is metabolised in the liver to sodium bicarbonate.

5.3 Preclinical safety data

No data available

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name	Specification Reference	%w/v
Water for Injections in bulk BP	EP	To 100
Hydrochloric Acid BP	EP	QS
Sodium Hydroxide BP	BP	QS

6.2 Incompatibilities

Incompatible with amikacin, amphotericin B, benzylpenicillin, dobutamine, amiodarone, amsacrine, sodium nitroprusside, tetracyclines, sodium bicarbonate, sodium calcium edetate and sulphadiazine sodium.

6.3 Shelf life

Semi-rigid, cylindrical neutral polythene container with a 'Twist-off' seal: 60 months.

Polyethylene bottle with cap and administration/addition points: 36 months.

6.4 Special precautions for storage

Store between 2°C -25°C

6.5 Nature and contents of container

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

Or

Polyethylene bottle with a cap with an administration point and an addition point (KabiPac).

The container holds 500 or 1000 ml.

6.6 Special precautions for disposal

Do not dilute before use.

Use standard sterile peritoneal dialysis equipment.

7 MARKETING AUTHORISATION HOLDER

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WA7 1NT

8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0045

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