SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hartmann's Solution for Injection BP as Steriflex No. 11 or **free***flex*

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Steriflex No. 11 has the following composition:

Name	Specification Reference	%w/v
Sodium Chloride for Injections	EP	0.6
Potassium Chloride BP	EP	0.04
Calcium Chloride BP Dihydrate	EP	0.027
Lactic Acid BP	EP	
Sodium Hydroxide BP		
Lactic Acid BP and Sodium Hydroxide BP are added in the form of 2M Sodium Lactate Solution or a Premade 50% Sodium Lactate Solution to produce a concentration of Sodium Lactate of		0.317

3 PHARMACEUTICAL FORM

Intravenous infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Steriflex No. 11 is indicated for the treatment of metabolic acidosis and dehydration with acidosis. It may be used to expand extracellular fluids or restore extracellular electrolyte in practically all patients. It may be used in the treatment of diabetic coma.

4.2 Posology and method of administration

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 products with lower sodium concentration compared to serum sodium concentration.

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

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

For intravenous infusion.

4.3 Contraindications

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. Steriflex No.11 should not be given to patients with cardiac arrhythmias. Lactate containing solutions are contraindicated in, patients with liver disease

4.4 Special warnings and precautions for use

Although Steriflex No. 11 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 Steriflex No. 11 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.

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 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 complications, because these patients are particularly vulnerable to the effects of brain swelling caused by acute hyponatraemia.

Do not use unless the solution is clear and free from particles.

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 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, e.g.: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action, e.g.: Chlorpropamide, NSAIDs, cyclophosphamide
- Vasopressin analogues, e.g.: 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

The safety of this product during pregnancy and lactation has not been assessed, but its use during these periods is not considered to constitute a hazard.

Hartmann's Solution for Injection 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 vein is always a possibility 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 authorization 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. Website: 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

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

Not 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.

Because of the nature of the plastic material of the Steriflex bag (PVC), this solution should not be used as a vehicle for the administration of drugs which may be sorbed to the surface of the bag to varying and significant degrees.

6.3 Shelf life

500 & 1000ml PVC Bags - 24 months.
500 & 1000ml Polyolefin Bags – 36 months.

6.4 Special precautions for storage

Store between 2°C and 25°C.

6.5 Nature and contents of container

The container is a flexible 500 or 1000ml bag made of medical grade PVC.

The bag is sealed either in:
A hermetically sealed polythene bag or
A rectangular pouch consisting of polyamide/polythene composite or
Polyamide/Polyethylene-Propylene composite laminate welded to polypropylene ethylene propylene composite plugged with a polycarbonate plug with either a bromobutyl - (West 4481/45) or gum (West 7006/45) stopper

or

A flexible 500 or 1000ml polyolefine bag sealed in a polyolefine overwrap.

6.6 Special precautions for disposal

Opening the overwrap:
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.
Setting up the solution:
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 08828/0083

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10 DATE OF REVISION OF THE TEXT

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