SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Sodium Chloride 0.9% Intravenous Infusion BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Sodium Chloride: 9.0 g/l
Each ml contains 9 mg sodium chloride.
For a full list of excipients: see 6.1

3. PHARMACEUTICAL FORM
Solution for infusion
Clear solution, free from visible particles.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications
“Sodium chloride 0.9% intravenous infusion is indicated for”:
- Treatment of isotonic extracellular dehydration
- Treatment of sodium depletion
- Vehicle or diluent of compatible drugs for parenteral administration.

4.2. Posology and method of administration
Adults, the Elderly and Children
Doses may be expressed in terms of mEq or mmol of sodium, mass of sodium, or mass of sodium salt (1 g NaCl = 394 mg, 17.1 mEq or 17.1 mmol of Na and Cl).
The concentration and dosage of sodium chloride solution for intravenous use is determined by several factors including the age, weight, and clinical condition of the patient and in particular the patient's hydration state. Serum-electrolyte concentrations should be carefully monitored.
The recommended dosage for treatment of isotonic extracellular dehydration and sodium depletion is:
- for adults: 500 ml to 3 Litres /24h
- for babies and children: 20 to 100 ml per 24 h and per kg of body weight, depending on the age and the total body mass.
The infusion rate depends on the patient clinical condition.
The recommended dosage when used as a vehicle or diluent ranges from 50 to 250 ml per dose of medicinal product to be administered.
When sodium chloride 0.9% is used as a diluent for injectable preparations of other drugs, the dosage and the infusion rate will be principally dictated by the nature and the dose regimen of the prescribed drug.
Administration
The solution is for administration by intravenous infusion.

4.3. Contra-indications
The solution is contra-indicated in patient presenting hypernatremia or hyperchloremia.
The contra-indications related to the added medicinal product should be considered.
4.4. Special warning and precautions for use

Special clinical monitoring is required at the beginning of any intravenous infusion. Administration should be carried out under regular and careful surveillance. Clinical and biological parameters, in particular serum-electrolytes, should be monitored.

Premature or term infants may retain an excess of sodium due to immature renal function. In premature or term infants, repeated infusions of sodium chloride should therefore only be given after determination of the serum sodium level.

Sodium chloride must be used with caution in patients with hypertension, heart failure, peripheral or pulmonary edema, impaired renal function, pre-eclampsia, aldosteronism, or other conditions and treatment (e.g. corticosteroids) associated with sodium retention.

For information on preparation of the product and additives, please see section 6.6.

4.5. Interaction with other medicinal products and other forms of interaction

None known.

4.6. Fertility, pregnancy and lactation

Can be used during pregnancy and lactation.

4.7. Effects on ability to drive and use machines

None known.

4.8. Undesirable effects

Undesirable effects are not expected in the usual treatment conditions.

Adverse reactions may be associated with the technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

General adverse effects of sodium excess are described in the Overdose section.

When sodium chloride 0.9% is used as a diluent for injectable preparations of other drugs, the nature of additives will determine the likelihood of any other undesirable effect.

If an adverse reaction to the added medicinal product does occur, discontinue the infusion, evaluate the patient, institute appropriate counter measures and save the remainder of the fluid for examination if deemed necessary.

4.9. Overdose

General adverse effects of sodium excess in the body include nausea, vomiting, diarrhea, abdominal cramps, thirst, reduced salivation and lacrimation, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary edema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma, and death.

Excessive administration of sodium chloride may cause hypernatremia and should be treated by an attending specialised physician.

Excess chloride in the body may cause a loss of bicarbonate with an acidifying effect.

When sodium chloride 0.9% is used as a diluent for injectable preparations of other drugs, the signs and symptoms of over infusion will be related to the nature of the additives being used. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant and supportive measures should be provided as necessary.
5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Pharmacotherapeutic group: “Other IV Solution Additives”
ATC code: B05XX

Sodium Chloride 0.9% intravenous infusion is an isotonic solution, with an approximate osmolarity of 308 mOsm/l.

The pharmacodynamic properties of the solution are those of the sodium and chloride ions in maintaining the fluid and electrolyte balance. Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, and also in its renal metabolism.

5.2. Pharmacokinetic properties
Sodium is predominantly excreted by the kidney, but there is extensive renal reabsorption. Small amounts of sodium are lost in the feces and sweat.

5.3. Preclinical safety data
The safety of sodium chloride in animals is not relevant in view of its presence as a normal component in animal and human plasma.

6. PHARMACEUTICALS PARTICULARS

6.1. List of excipients
Water for Injections.

6.2 Incompatibilities
As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition.

It is the responsibility of the physician to judge the incompatibility of an additive medication with the Sodium Chloride 0.9% Intravenous Infusion solution by checking for eventual color change and/or eventual precipitate, insoluble complexes or crystals apparition. The Instructions for Use of the medication to be added must be consulted.

Before adding a drug, verify:
- It is soluble and stable in water at the pH range of the Sodium Chloride 0.9% Intravenous Infusion solution

When a compatible medication is added to the Sodium Chloride Intravenous Infusion, the solution must be administered immediately.

Those additives known to be incompatible should not be used.

6.3 Shelf life
Shelf life as packaged:
50 ml bag: 15 months
100 ml bag: 2 years
250 and 500 ml bags: 2 years
1000 ml bags: 3 years

In-use shelf life: Additives.

Chemical and physical stability of any additive at the pH of Sodium Chloride 0.9% Intravenous Infusion in the Viaflo container should be established prior to use.
From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4

Special precautions for storage

50 and 100 ml bags: Do not store above 30°C.
250, 500 and 1000 ml bags: This medicinal product does not require any special storage conditions.

6.5 Nature and contents of containers

Bag sizes: 50, 100, 250, 500 or 1000mL

The bags known as Viaflo are composed of polyolefin/polyamide co-extruded plastic (PL-2442).

The bags are overwrapped with a protective plastic pouch composed of polyamide/polypropylene.

Pack sizes:
- 50 bags of 50 ml per carton
- 1 bag of 50 ml
- 50 bags of 100 ml per carton
- 1 bag of 100 ml
- 30 bags of 250 ml per carton
- 1 bag of 250 ml
- 20 bags of 500 ml per carton
- 1 bag of 500 ml
- 10 bags of 1000 ml per carton
- 1 bag of 1000 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed. Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

Additives may be introduced before infusion or during infusion through the injection site

When additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

Adding other medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Discard after single use.

Discard any unused portion.
Do not reconnect partially used bags.
Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.

Opening
- Remove the Viaflo container from the overpouch just before use.
- Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired
- Check solution for limpidity and absence of foreign matter. If solution is not clear or contains foreign matter, discard the solution.

Preparation for administration
Use sterile material for preparation and administration.
- Suspend container from eyelet support.
- Remove plastic protector from outlet port at bottom of container:
  - grip the small wing on the neck of the port with one hand
  - grip the large wing on the cap with the other hand and twist,
  - the cap will pop off.
- Use an aseptic method to set up the infusion.
- Attach aseptic method to set up the infusion.

Techniques for injection of additive medications
Warning: Additives may be incompatible.

To add medication before administration
- Disinfect medication site.
- Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.
- Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

Caution: Do not store bags containing added medications.

To add medication during administration
- Close clamp on the set
- Disinfect medication site.
- Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
- Remove container from IV pole and/or turn to an upright position.
- Evacuate both ports by tapping gently while the container is in an upright position.
- Mix solution and medication thoroughly.
- Return container to in use position, re-open the clamp and continue administration.

7. MARKETING AUTHORISATION HOLDER
Baxter Healthcare Ltd.
Caxton Way, Thetford
Norfolk IP24 3SE
United Kingdom

8. MARKETING AUTHORISATION NUMBER
PL 00116/0334

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORIZATION
Date of first authorisation: 10 May 2001
Date of latest renewal: 19 March 2006

10. **DATE OF REVISION OF THE TEXT**
02 Oct 2012