Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

0.9% Sodium Chloride Intravenous Infusion Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride 9g per litre.

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Colourless to faintly straw-coloured solution without visible particles in bags, individually overwrapped.

pH 5. Osmolarity approx 300mOsm/kgH_2O.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

0.9% isotonic saline solution is indicated:

- for fluid replacement and provision of extracellular ions in near physiological concentration in conditions of extracellular-volume depletion, dehydration and electrolyte imbalance such as sodium depletion

- as an isotonic medium for intravenous administration of medicinal products known to be compatible with 0.9% sodium chloride.

4.2 Posology and method of administration

For intravenous infusion under medical supervision.
Single use only.

The pathophysiological response to dehydration, to electrolyte loss and to sodium chloride infusion will vary with the age of the patient being treated and this should be taken into account during rehydration therapy. Fluid replacement therapy should be administered with caution to very young and elderly patients.

The volume of isotonic saline solution needed to replenish fluid deficits varies with age, body weight, complementary treatment and severity of the clinical condition. The dose and rate of administration are subject to clinical and laboratory assessment in each case.

4.3 Contraindications

Sodium chloride infusion solution should be administered with caution to:

- patients with conditions of impaired sodium excretion such as impaired renal function, cardiac failure, cardio-pulmonary disease, peripheral or pulmonary oedema, hypertension, cirrhosis of the liver, pre-eclampsia, severe hepatic insufficiency; hypernatraemia
- patients receiving drugs which may promote salt retention, and
- very young and to elderly patients who have reduced capacity to compensate for fluctuations in fluid and electrolyte balance.

4.4 Special warnings and precautions for use

Electrolytes should be monitored prior to and during infusion.

4.5 Interaction with other medicinal products and other forms of interaction

Check compatibility of medicinal products with 0.9% sodium chloride before administration with the solution.

See Section 6.2 Incompatibilities.

4.6 Fertility, pregnancy and lactation

Administration of intravenous fluids to pregnant or lactating women requires special consideration of the consequences of possible unwanted effects in relation to the desired therapeutic objective.

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

Infusion of 0.9% sodium chloride infusion may lead to fluid and electrolyte imbalances such as metabolic acidosis, hypokalaemia, sodium retention, hypertension, tachycardia, oedema and gastrointestinal effects. Prolonged intravenous infusion may lead to venous irritation and thrombophlebitis at the infusion site. In the event of adverse reaction, stop infusion immediately.

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 national reporting system:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie.
E-mail: medsafety@hpra.ie

4.9 Overdose

Excessive administration may give rise to sodium accumulation and hypernatraemia with resultant dehydration of organs particularly the brain, and oedema, hypervolemic haemodilution, and hypokalaemia.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic: electrolyte ATC code B05BB01

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

6.2 Incompatibilities

No studies for compatibility have been conducted with this product. Confirm additive compatibility before use.

6.3 Shelf life

2 years
Use immediately on removal from overwrap.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze. Store in the outer container.

6.5 Nature and contents of container

COSINUS^{PVC} and COSINUS containers: COSINUS^{PVC} flexible PVC container with a PVC infusion site, or COSINUS flexible ethylene and polypropylene copolymer container and infusion site; and polycarbonate-polyisoprene or polypropylene-polyisoprene injection site for addition of medicinal products. Bags are individually overwrapped in transparent polypropylene laminate. Bags contain 50ml, 100ml, 250ml, 500ml or 1000ml solution.

Easyflex N and Easyflex + containers: flexible ethylene and polypropylene copolymer container with a polycarbonate-silicon needleless access site for addition of medicinal products or for use as a luer lock connection for infusion. Bags are individually overwrapped in transparent polypropylene laminate. Bags contain 50ml, 100ml, 250ml, 500ml or 1000ml solution.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only.

Do not use unless the solution is clear and the container undamaged. Discard any unused solution. Any unused product or waste material should be disposed of in accordance with local requirements.

COSINUS^{PVC} and COSINUS bags:
Remove the bag from the plastic overwrap. Remove the protector and connect by clamping to the administration set.

Addition of medicinal products:
Confirm additive compatibility before use.
Clean the injection site using antiseptic solution.
Carefully introduce the sterile needle into the sterile chamber in the injection site, attach the needle to the container with the medicinal product, introduce the needle through the second membrane into the bag and inject the medicine. Carefully withdraw the needle.
Mix thoroughly with the solution. Use immediately.

Easyflex N and Easyflex + bags:

Remove the bag from the plastic overwrap.
Do not use needles or spikes to gain access to the needleless connector site

Connection of syringes to the needleless connector for the injection of a medicine or aspiration of solutions

1. Confirm additive compatibility before use.
2. Clean the injection site using antiseptic solution.
3. Attach the male luer-lock connector of the syringe with the bag's needleless connector by pushing in and twisting the syringe clockwise to secure the connection.
4. Aspirate the IV solution out of the bag, or inject the fluid or medicine into the bag. Mix thoroughly with the solution. Use immediately.
5. Disconnect the syringe from the needleless connection site by twisting anti-clockwise.
6. The needleless connection site closes automatically.
7. The needleless connection site can be reconnected several times by repeating steps 1 to 3.

Connection of an IV giving set with a spike for the administration of an IV solution:

Easyflex N:
- Remove the protective cover (twist-off);
- Connect the giving set to the bag by piercing the port and fully insert the giving set using a rotating movement.
- Administer IV fluid or medicine.

Easyflex +:
- Remove the infusion site protector by breaking it;
- Connect the giving set to the bag by piercing the port without rotating movement.
- Administer IV fluid or medicine

Connection of an IV giving set with a male luer-lock connector to the needleless connector for the administration of an IV solution

Use the needleless connector to infuse an IV solution with a giving set fitted with a male luerlock connector.
1. Clean the injection site using antiseptic solution. Attach the male luer-lock connector of the IV giving set with the female luer of the bag's needleless connection site by pushing in and twisting the set clockwise to secure the connection.
2. Administer IV fluid or medicine in the usual manner
3. Disconnect the giving set from the needleless connection site by twisting the luer-lock connection anti-clockwise.
4. The needleless connection site closes automatically.

7 MARKETING AUTHORISATION HOLDER

Laboratoire Aguettant
1 Rue Alexander Fleming
Lyon
69007
France

8 MARKETING AUTHORISATION NUMBER

PA1968/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31 May 1999

Date of last renewal: 15 March 2006

10 DATE OF REVISION OF THE TEXT

December 2025