# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

5% Glucose Intravenous Infusion Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dextrose (glucose) monohydrate equivalent to 50.00g anhydrous dextrose per litre.
278mmol/l. Approximately 836 kJ/litre (200 kcal/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 4.15.- Osmolality approx 300mOsm/kg$H_2O$.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

5% Glucose Intravenous Infusion Solution is indicated for:

- fluid replacement, administered alone or in regimens with electrolytes or additives known to be compatible with 5% glucose
- medium for intravenous administration of medicinal products known to be compatible with 5% glucose

### 4.2 Posology and method of administration

Fluid balance, serum glucose, serum sodium and other electrolytes may need to be monitored before and during administration, especially 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 hyponatraemia. Monitoring of serum sodium is particularly important for physiologically hypotonic fluids. 5% Glucose Intravenous Infusion Solution may become extremely hypotonic after administration due to glucose metabolization in the body (see sections 4.4, 4.5 and 4.8).

To avoid dehydration in a healthy adult or in patients with no complicating factors such as fever or excessive fluid losses, daily fluid requirements are 1.5 to 2.5 litres. The volume of glucose solution needed to replenish deficits will vary with body weight, complementary treatment, severity of the clinical condition and hydration status of the patient, but in adults will usually lie between 2 and 10 litres. The pathophysiological response to dehydration, to electrolyte loss and to glucose infusion will vary with the age of the patient being treated and this should be taken into account during rehydration therapy. There is no recommended dose as this is a matter for clinical judgment and laboratory assessment in each case. The dose range is typically 500 – 3000ml in a 24 hour period and typical maximum rates are 800mg/kg/hr or 600ml/hr.

For intravenous infusion under medical supervision.
Single use only.

### 4.3 Contraindications

Hyperglycaemia. Conditions of water excess

### 4.4 Special warnings and precautions for use

- The rate of infusion should be sufficiently slow to allow detection of osmotic diuresis

- Prior to and during infusion, serum and/or urinary electrolytes and glucose should be monitored to assess the nature and severity of fluid depletion and electrolyte imbalance. Close monitoring of patients with diabetes mellitus, and in patients with renal failure, is necessary during glucose infusion.
- Glucose infusions are incompatible with blood for transfusion as haemolysis or clumping can occur; do not administer through the same infusion equipment as blood or blood components for transfusion (either before, during or after their administration)
- Use with care in patients who have suffered an acute ischaemic stroke.

Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization (see section 4.2).
Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia.

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 (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain 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, and cerebral contusion) 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 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.

Check compatibility of medicinal products with 5% glucose before administration with the solution. See section 6.2 Incompatibilities.

**4.6 Fertility, pregnancy and lactation**

It is particularly important to avoid maternal hyperglycaemia during intravenous glucose infusion in the perinatal period in view of the possibility of inducing neonatal hypoglycaemia.

5% Glucose Intravenous Infusion Solution should be administrated with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see sections 4.4, 4.5 and 4.8).

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

Not relevant.

**4.8 Undesirable effects**

The frequency of adverse events listed below is defined using the following convention:

very common (≥1/10); common (≥1/100 to < 1/10); uncommon (≥1/1,000 to < 1/100); rare (≥1/10,000 to < 1/1,000); very rare (< 1/10,000), not known (cannot be estimated from the available data).

Metabolism and nutrition disorders
Not known: fluid and electrolyte disturbances including hypokalaemia, hypomagnesaemia and hypophosphataemia, hyperglycaemia, glycosuria. Hypokalaemia may complicate glucose infusions, especially when combined with insulin in the treatment of diabetic ketoacidosis.
Not known: Hospital Acquired Hyponatraemia*

General and administration site disorders
Not known: Irritation and discomfort at the site of infusion

Nervous system disorders
Not known: Hyponatraemic encephalopathy*

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

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:
**For United Kingdom**
**Yellow Card Scheme**
Website: www.mhra.gov.uk/yellowcard

**For Ireland**
**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**

Administration of excessive amounts of 5% glucose may result in fluid overload and water intoxication. Severe over-infusion is usually limited to infusion with higher concentrations of glucose solutions, which may cause plasma hyperosmolality and osmotic diuresis. Treatment is symptomatic.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: electrolyte with carbohydrate

ATC code B05BB02.

Glucose is rapidly absorbed into cells and metabolized into carbon dioxide and water with the release of energy. 5% glucose intravenous infusion solution allows intracellular rehydration and glucose also serves as a carbohydrate source for cellular nutrition.

**5.2 Pharmacokinetic properties**

The maximum rate of glucose utilization has been estimated to be about 500-800 mg/ kg body weight /hour.

**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.

Glucose infusions are incompatible with blood for transfusion as haemolysis or clumping can occur; do not administer through the same infusion equipment as blood or blood components for transfusion (either before, during or after administration).

**6.3 Shelf life**

Before opening the overpack:
For PVC bags (COSINUS$^{PVC}$):
- 50, 100, 250 ml: 18 months
- 500 and 1 000 ml: 2 years
For polyolefin bags (COSINUS, Easyflex N, Easyflex+) : 2 years

After opening the overpack: Use immediately on removal from overwrap.

**6.4 Special precautions for storage**

Do not store above 25°C. Do not freeze. Store in the original 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 and provides valve safety.

**7 MARKETING AUTHORISATION HOLDER**

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1 Rue Alexander Fleming
Lyon
69007
France

**8 MARKETING AUTHORISATION NUMBER**

PA1968/019/001

**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**

April 2026