Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Glucose Intravenous Infusion BP 5% w/v solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 50 mg glucose as glucose monohydrate

1000 ml contain 50.0 g glucose (as glucose monohydrate, 55.0 g)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Infusion.
A clear, colourless or almost colourless aqueous solution.

Energy: 837 kJ/l 200 kcal/l

Theoretical osmolarity: 278 mOsm/l
Acidity titre (titration to pH 7.4): < 0.5 mmol/l NaOH
pH: 3.5 – 5.5

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

1. For use in prophylactic and replacement therapy requiring the use of glucose.
2. As a vehicle solution for compatible electrolyte concentrates and medicinal products.

4.2 Posology and method of administration

Posology

Fluid balance, serum glucose, 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. Glucose Intravenous Infusion BP 5 % w/v may become extremely hypotonic after administration due to glucose metabolisation in the body (see sections 4.4. 4.5 and 4.8).

Prophylactic and replacement therapy requiring the use of glucose
The quantity and rate of administration is dependent on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician.

Vehicle solution for compatible medicinal products
When used as a vehicle choose a volume that yields the desired degree of dilution of the medicament for which Glucose Intravenous Infusion BP 5 % w/v is to be used as diluent, having regard to the maximum dose stated below.

Of note, provision of the entire daily fluid supply with this solution alone is contraindicated. See sections **4.3** and **4.4**.

Adults
Maximum daily intake
Up to 40 ml per kg body weight per day, corresponding to 2 g of glucose per kg body weight per day

Maximum infusion rate
The maximum infusion rate is up to 5 ml per kg body weight per hour, corresponding to 0.25 g (250 mg) of glucose per kg body weight per hour.

When administering this solution the total daily fluid and glucose requirements should be taken into account.

Paediatric population
The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in paediatric intravenous fluid therapy. Generally, dosing of this solution should be as restrictive as possible and must be accompanied by adequate electrolyte substitution. See sections 4.3 and 4.4.
When administering this solution the total daily fluid and glucose requirements should be taken into account.

Method and route of administration

For intravenous infusion.
The possibility of peripheral venous infusion depends on the osmolarity of the prepared mixture.

4.3 Contraindications

Hyperglycaemia, not responding to insulin doses of up to 6 units insulin/hour;
Lactic Acidosis.

If it should be necessary to administer large volumes further contra-indications can arise on account of the glucose and/or fluid load:

- Hypotonic hyperhydration
- Isotonic hyperhydration
- Acute congestive heart failure
- Pulmonary oedema

This solution must not be used alone for fluid supply/rehydration because it does not contain electrolytes. See section 4.4.
This container contains a significant volume of air. To avoid risk of air embolism, this product must not be administered by pressure infusion.

4.4 Special warnings and precautions for use

Special warnings

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.
Consideration should be given to the correction of pre-existing thiamine (Vitamin B1) deficiency in at risk patients to prevent the development of Wernicke encephalopathy and/or lactic acidosis. **If there is a thiamine deficiency (vitamin B1 deficiency), an appropriate dose of thiamine should be given as soon as possible.**

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.

In patients with disturbed glucose metabolism, as present e.g. in postoperative or posttraumatic conditions, or in patients with diabetes mellitus,Glucose Intravenous Infusion BP 5 % w/v must be administered with caution, i.e. with frequent monitoring (see below), and dosage must be adapted as required.
States of hyperglycaemia should be adequately monitored and treated with insulin. The application of insulin causes additional shifts of potassium into the cells and may therefore cause or increase hypokalaemia.
Patient monitoring should include regular checks of the blood glucose level.
This fluid should also be administered with great caution to patients with renal insufficiency.
Administration of glucose solutions is not recommended after acute ischaemic strokes as hyperglycaemia has been reported to worsen ischaemic brain damage and impair recovery. In prehospital management of acute ischemic stroke, glucose-containing solutions should be avoided unless hypoglycaemia is present or strongly suspected.
Glucose Intravenous Infusion BP 5 % w/v must not be administered in the same infusion
equipment, simultaneously, before, or after administrationof blood products because of the possibility of pseudo-agglutination.

Paediatric population
Intravenous fluid therapy should be closely monitored in the paediatric population as they may have impaired ability to regulate fluids and electrolytes. Adequate hydration and urine flow must be ensured and careful monitoring of fluid balance, plasma and urinary electrolyte concentrations are mandatory**.**

The infusion of hypotonic fluids such as Glucose Intravenous Infusion BP 5 % w/v together with the non-osmotic secretion of ADH (in pain, anxiety, the post-operative state, nausea, vomiting, pyrexia, sepsis, reduced circulating volume, respiratory disorders, CNS infections, and metabolic and endocrine disorders) may result in hyponatraemia. Hyponatraemia can lead to headache, nausea, seizures, lethargy,
coma, cerebral oedema and death, therefore acute symptomatic hyponatraemia (e.g.
hyponatraemic encephalopathy) is considered a medical emergency.

Special precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions with medicinal products with an influence on glucose metabolism should be considered.
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.

Prescribers should refer to the information provided with the product concerned.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are limited data (less than 300 pregnancy outcomes) from the use of glucose monohydrate in pregnant women. Animal studies do not indicate direct or indirect harmful effects at the therapeutic does with respect to reproductive toxicity (see section 5.3).
Glucose Intravenous Infusion BP 5 % w/v can be used during pregnancy, if indicated as vehicle solution.

Glucose Intravenous Infusion BP 5 % w/v 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 section 4.4, 4.5 and 4.8).

Breast-feeding
Glucose/metabolites are excreted in human milk, but at therapeutic doses of Glucose Intravenous Infusion BP 5 % w/v no effects on the breast-fed newborns/infants are anticipated.
Glucose Intravenous Infusion BP 5 % w/v can be used during breast-feeding as indicated.

Fertility
No data available.

4.7 Effects on ability to drive and use machines

Glucose Intravenous Infusion BP 5 % w/v has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects are listed according to their frequencies as follows:
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 (frequency cannot be estimated from the available data)

Metabolism and nutrition disorders:
Not known: Electrolyte imbalance, e.g. hyponatraemia and hypokalaemia.

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).

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 HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

4.9.1 Symptoms

Symptoms of glucose overdose
Excessive glucose infusions can cause hyperglycaemia, glucosuria, hyperosmolar dehydration and in extreme cases overdose can lead to hyperglycaemic-hyperosmolar coma.

Symptoms of fluid overdose
Fluid overdose may result in hyperhydration with increased skin tension, venous congestion, oedema edema ncreased skin tension, voedema -, dilution of serum electrolytes, electrolyte imbalances, notably hyponatraemia and hypokalaemia (see section **4.4**), and acid-base imbalances.

Clinical symptoms of water intoxication may occur like nausea, vomiting, spasms.

Further symptoms of overdose may arise depending on the nature of the additive.

4.9.2 Emergency treatment, antidotes

The disturbances can - depending on the type and the degree of severity - be treated by stopping the infusion, by administration of electrolytes, diuretics, or insulin.

For correction of hyponatraemia the following formula(1) can be used:

mmol of Na^+ required = (target Na^+ level(2)– actual Na^+ level) × TBW(3)

(1) modified from [2])
(2) should not be lower than 130 mmol/l
(3) TBW: Total body water, calculated as a fraction of body weight: 0.6 in children, 0.6 and 0.5 in nonelderly men and women, respectively, and 0.5 and 0.45 in elderly men and women, respectively

During treatment, serum electrolytes should be monitored.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group:
Solvents and diluting agents incl. irrigating solutions
ATC code: V07AB

Pharmacodynamic effects
Low concentration glucose solutions are suitable diluents for drugs because glucose, as a natural substrate of the cells in the organism, is ubiquitously metabolised. Under physiological conditions glucose is the most important energy supplying carbohydrate with a caloric value of approximately 17 kJ/g or 4 kcal/g.
In adults, the normal concentration of glucose in blood is reported to be 70 – 100 mg/100 ml, or 3.9 – 5.6 mmol/l (fasting).

5.2 Pharmacokinetic properties

Absorption
Since the solution is administered intravenously, its bioavailability is 100 %.

Distribution
On infusion glucose initially distributes in the intravascular space and is then taken up in the intracellular space.

Biotransformation
In glycolysis, glucose is metabolized to pyruvate. Under aerobic conditions pyruvate is completely oxidised to carbon dioxide and water. In case of hypoxia, pyruvate is converted to lactate. Lactate can be partially reintroduced into the glucose metabolism (CORI cycle).

Glucose utilisation disturbances (glucose intolerance) can occur under pathological metabolic conditions. These are primarily diabetes mellitus, states of metabolic stress (e.g. intra-, and postoperatively, severe disease, injury), and hormonally induced reduction of glucose tolerance, which can lead to hyperglycaemia even without exogenous glucose intake. Hyperglycaemia can - depending on its degree - lead to osmotically mediated renal fluid losses with consequent hypertonic dehydration, to hyperosmotic disorders up to and including hyperosmotic coma.

Metabolism of glucose and electrolytes are closely related to each other. Insulin facilitates potassium influx into cells. Phosphate and magnesium are involved in the enzymatic reactions associated with glucose utilization. Potassium, phosphate and magnesium requirements may therefore increase following glucose administration and may therefore have to be monitored and supplemented according to individual needs. Especially cardiac and neurological functions may be impaired without supplementation.

Elimination
The final products of the complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidneys (water). Practically no glucose is excreted renally by healthy persons. In pathological metabolic conditions associated with hyperglycaemia (e.g. diabetes mellitus, postaggression metabolism), glucose is also excreted via the kidneys (glucosuria) when (at blood glucose levels higher than 160 - 180 mg/dl or 8.8 her thmmol/l) the maximum tubular resorption capacity is exceeded.

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 and development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

Because Glucose Intravenous Infusion BP 5% w/v has an acid pH incompatibilities can occur on mixing with other medicinal products.

Erythrocyte concentrates must not be suspended in Glucose Intravenous Infusion BP 5% w/v because of the risk of pseudoagglutination.

See also section 4.4.

6.3 Shelf life

- **Unopened:**

Container: 3 years

- **After first opening the container:**

Containers once opened must be used immediately. See section 6.6.

– after admixture of additives
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

6.4 Special precautions for storage

Do not store above 25 . Store in the original container.
For storage conditions after admixture of additives see section 6.3.

6.5 Nature and contents of container

Containers of low-density polyethylene Ecoflac Plus® with integral on-welded closure of the same material.
The closure contains a rubber disc.
Contents 250 ml, 500 ml, 1000 ml:
available in packs of
10 × 250 ml
10 × 500 ml
10 × 1000 ml

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
The medicinal product is supplied in containers for single use only.
After first use discard container and remaining contents. Do not re-connect partially used containers.
Only to be used if solution is clear and colourless or almost colourless and if the container or its closure are undamaged.
Administration should commence immediately after connecting the container to the giving set or infusion equipment.

When admixing additives observe usual precautions of asepsis strictly.

7 MARKETING AUTHORISATION HOLDER

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Carl-Braun-Straße 1
34212 Melsungen
Germany

8 MARKETING AUTHORISATION NUMBER

PA0736/045/001

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