# Glucose Intravenous Infusion B.P. 5% w/v

## 1. NAME OF THE MEDICINAL PRODUCT

Glucose Intravenous Infusion B.P. 5% w/v

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution contains
Glucose 50.0 mg
(as glucose monohydrate, 55.0 mg)

100 ml of solution contains
Glucose 5.0 g
(as glucose monohydrate, 5.5 g)

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless solution free from particles.

Energy: 837 kJ/l = 200 kcal/l
Theoretical osmolarity: 278 mOsm/l

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

- Carbohydrate solution for intravenous liquid therapy
- Vehicle solution for compatible medicinal products

### 4.2 Posology and method of administration

**Carbohydrate solution for intravenous liquid therapy**

The dosage depends on the age, weight, clinical and physiological (acid-base balance) conditions of the patient. The concomitant therapy should be determined by the consulting specialist.

**Vehicle solution for compatible medicinal products**

The volume to be chosen depends on the desired concentration of the medicinal product for which the solution is to be used as vehicle having regard to the maximum dose stated below.

Posology

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. Glucose 50 mg/ml solution for infusion may become hypotonic after administration due to glucose metabolisation in the body (see sections 4.4. 4.5 and 4.8).

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

The maximum daily dose for Glucose Intravenous Infusion B.P. 5% w/v results from the maximum daily fluid demand and should not exceed 40 ml per kg body weight per day, corresponding to 2 g of glucose per kg body weight per day.

If clinically required, the dose might be exceeded in exceptional cases but must not exceed the patient's maximum glucose oxidation capacity ranging from 5 mg per kg per min for adults to 10-18 mg per kg per min for babies and children depending on the age and the total body mass.

Maximum infusion rate

Up to 5 ml per kg body weight per hour, corresponding to 0.25 g of glucose per kg body weight per hour.

*Paediatric population*

The recommended dosage for treatment fluid depletion is:
- 0-10 kg body weight: 100 ml/kg/24 h
- 10-20 kg body weight: 1000 ml + 50 ml /kg for each kg > 10 kg/24 h
- > 20 kg body weight: 1500 ml + 20 ml / kg for each kg > 20 kg/24 h

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.

Method of administration

Intravenous use.

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

### 4.3 Contraindications

- Hypersensitivity to the active substance. See section 4.4 and 4.8 for corn allergies
- Hyperglycaemia, not responding to insulin doses of up to 6 units insulin/hour
- Lactic acidosis

If it is necessary to administer large volumes, further contraindications can arise on account of the 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**.

### 4.4 Special warnings and precautions for use

Special warnings

Glucose B.Braun 50 mg/ml is an isotonic solution. In the body, however, glucose containing fluids can become hypotonic due to rapid glucose metabolization (see section 4.2).

Depending on the tonicity of the solution, 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.

Due to the risk of developing a severe lactic acidosis and/or a Wernicke encephalopathy a pre-existing thiamine (Vitamin $B_1$) deficiency must be corrected before infusion of glucose containing solutions.

*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.

Electrolyte-free carbohydrate solutions must not be used for fluid substitution, especially rehydration therapy, without adequate electrolyte administration, because this could lead to markedly decreased serum electrolyte values, notably severe hyponatraemia and hypokalaemia, with potentially detrimental effects on the patient, e.g. brain damage or heart affections. Especially children, elderly patients and patients in poor general condition are at risk.

Serum electrolytes, fluid and acid-base balance should be monitored. Especially, adequate sodium and – in relation to glucose metabolism – potassium supply should be ensured. In states of electrolyte deficiencies like hyponatraemia or hypokalaemia the solution must not be used without adequate electrolyte substitution.

In patients with disturbed glucose metabolism, as present e.g. in postoperative or posttraumatic conditions or in patients with diabetes mellitus, Glucose Intravenous Infusion B.P. 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.

Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, have been reported with Glucose solutions (see section 4.8). Solutions containing glucose should therefore be used with caution, if at all, in patients with known allergy to corn or corn products (see section 4.3).

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Glucose solutions should not be administered through the same infusion equipment, simultaneously before, or after administration of blood, 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.

Please note: The safety information of the additive provided by the respective manufacturer has to be taken into account.

### 4.5 Interactions 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 from the use of glucose solutions in pregnant women. Animal studies do not indicate direct or indirect harmful effects at the therapeutic doses with respect to reproductive toxicity (see section 5.3).

Intrapartum maternal intravenous glucose infusion may result in foetal insulin production, with an associated risk of foetal hyperglycaemia and metabolic acidosis as well as rebound hypoglycaemia in the neonate.

Glucose Intravenous Infusion B.P. 5% w/v can be used during pregnancy. Careful monitoring of blood glucose is necessary. Caution should be exercised when glucose solution is used intrapartum.

Glucose Intravenous Infusion B.P. 5% w/v should be administrated with special caution for pregnant women during labour particularly if administered in combination with oxytocin (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 B.P. 5% w/v no effects on the breast-fed newborns/infants are anticipated.

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

When used as vehicle solution the safety information of the additive provided by the respective manufacturer has to be taken into account.

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### 4.8 Undesirable effects

Undesirable effects which occurred in patients treated with Glucose Intravenous Infusion B.P. 5% w/v are tabulated below.
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)

| Tabulated list of adverse reaction | | |
|---|---|---|
| System Organ Class | Adverse reaction (MedDRA term) | Frequency |
| Immune system disorders | Anaphylactic reaction*<br>Hypersensitivity* | Not known |
| Skin and subcutaneous tissue disorders | Rash | Not known |
| Vascular disorders | Venous thrombosis<br>Phlebitis | Not known |
| General disorders and administration site conditions | Chills*<br>Pyrexia*<br>Infusion site infection<br>Infusion site irritation for example erythema<br>Extravasation<br>Local reaction<br>Pain localised | Not known |
| Metabolism and nutrition disorders | Electrolyte imbalance, e.g. hyponatraemia and hypokalaemia<br>Hospital Acquired Hyponatraemia** | Not known |
| Neurological disorders | Hyponatraemic encephalopathy** | Not known |

*Potential manifestation in patients with allergy to corn, see section 4.4.
**Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

### 4.9 Overdose

*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 – possibly also lung or brain oedema –, 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.

*Treatment*

Depending on type and severity of the disorders:
Immediate stop of infusion, administration of electrolytes, diuretics, or insulin.
For correction of hyponatraemia the following formula can be used:

$$mmol\ of\ Na^+\ required = (target\ Na^+\ level^{(1)} - actual\ Na^+\ level) \times TBW^{(2)}$$

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

During treatment, serum electrolytes should be monitored.

For treatment of symptoms resulting from overdose of an additive the instructions given by the manufacturer of the respective additive must be followed.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic 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 approx. 17 kJ/g or 4 kcal/g. In adults, the normal concentration of glucose in blood is reported to be 70 – 100 mg/dl or 3.9 – 5.6 mmol/l (fasting).

### 5.2 Pharmacokinetic properties

Absorption

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

Distribution

After infusion, glucose is first distributed in the intravascular space and then is taken up into the intracellular space.

Biotransformation

In glycolysis, glucose is metabolised 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 conditions of pathological metabolism. These mainly include diabetes mellitus and states of metabolic stress (e.g. intra-, and postoperatively, severe disease, injury), hormonally mediated depression of glucose tolerance, which can even lead to hyperglycaemia without exogenous supply of the substrate. Hyperglycaemia can – depending on its severity – lead to osmotically mediated renal fluid losses with consecutive 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 – 9.9 mmol/l) the maximum tubular reabsorption capacity is exceeded.

### 5.3 Preclinical safety data

No non-clinical studies have been carried out with Glucose Intravenous Infusion B.P. 5% w/v. Glucose is a physiological component of animal and human plasma. Limited toxicological data with different glucose solutions for infusion reveal at therapeutic doses no special hazard for humans.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Water for injections

### 6.2 Incompatibilities

Because Glucose Intravenous Infusion B.P. 5% w/v has an acidic pH, incompatibilities can occur on mixing with other medicinal products and with blood.

Information on compatibility can be requested from the manufacturer of the added drug.

Erythrocyte concentrates must not be suspended in Glucose Intravenous Infusion B.P. 5% w/v because of the risk of pseudo-agglutination. See also section 4.4.

### 6.3 Shelf life

*Unopened*

- Polyethylene bottle, glass bottle: 3 years
- Plastic bag "Ecobag" 100 ml: 20 months
- Plastic bag "Ecobag" 250 ml, 500 ml, 1000 ml: 2 years

- *after first opening the container*

Once containers are opened contents must be used immediately. See section 6.6.

- *after addition 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 and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Observe the directions given by the manufacturer of the respective additive or drug to be diluted.

### 6.4 Special precautions for storage

The product should not be stored above the temperature stated on the label.
For storage conditions after addition of additives see section 6.3.

### 6.5 Nature and contents of container

Bottles of colourless low-density polyethylene (LDPE),
contents: 100 ml, 250 ml, 500 ml, 1000 ml
available in packs of:
20 × 100 ml
30 × 250 ml
10 × 500 ml
10 × 1000 ml

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Containers are for single use only. Discard container and any unused content after use. Do not re-connect partially used containers.

Only to be used if solution is clear and colourless or almost colourless, free from visible particles and if the container and its closure are undamaged.

Administration should commence immediately after connecting the container to the giving set or infusion equipment.

Before addition of an additive or preparing a nutrient mixture, physical and chemical compatibility must be confirmed. Because Glucose Intravenous Infusion B.P. 5% w/v has an acidic pH, incompatibilities can occur on mixing with other medicinal products. Information on compatibility can be requested from the manufacturer of the added drug.

When adding additives observe usual precautions of asepsis strictly.

## 7. DATE OF REVISION OF THE TEXT

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