# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

5 % w/v Glucose Intravenous Infusion BP

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution contains

Glucose 50.0 mg

(as glucose monohydrate, 55 mg)
100 ml of solution contains
Glucose 5.0 g
(as glucose monohydrate,5.5 g)

For excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless aqueous solution

| | |
|---|---|
| Energy: | 835 kJ/l  200 kcal/l |
| Theoretical osmolarity: | 278 mOsm/l |
| pH: | 3.5 – 5.5 |

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Carbohydrate solution for intravenous liquid therapy

- Vehicle solution for compatible medicinal product.

### 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. 5 % w/v Glucose Intravenous Infusion BP may become hypotonic after administration due to glucose and 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.

**Carbohydrate solution for intravenous liquid therapy**

The dosage depends on the age, weight, clinical and physiological (acid-base balance) conditions of the patient, having regard to the maximum dose states below. 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.

*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
Up to 5 ml per kg body weight per hour, corresponding to 0.25 g 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 dosage depends on the age, weight, clinical and physiological (acid-base balance) conditions of the patient, the concomitant therapy and should be determined by the consulting specialist.

Generally, dosing of this solution should be as restrictive as possible and must be accompanied by adequate electrolyte substitution. See also sections **4.3** and **4.4**.

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

The maximum daily dose, in g of glucose per kg body weight and in ml of solution per kg body weight per day, is for:

| | | |
|---|---|---|
| Pre-term neonates: | 18 g per kg body weight | 180 ml per kg body weight |
| Term neonates : | 15 g per kg body weight | 150 ml per kg body weight |
| 1st – 2nd year: | 15 g per kg body weight | 150 ml per kg body weight |
| 3rd – 5th year: | 12 g per kg body weight | 120 ml per kg body weight |
| 6th – 10th year: | 10 g per kg body weight | 100 ml per kg body weight |
| 11th – 14th year: | 8 g per kg body weight | 80 ml per kg body weight |

When administering this solution, the total daily fluid intake must be taken into account. The recommended daily parenteral fluid intake for children is as follows:

| | |
|---|---|
| 1st day of life: | 60 – 120 ml per kg body weight per day |
| 2nd day of life: | 80 – 120 ml per kg body weight per day |
| 3rd day of life: | 100 – 130 ml per kg body weight per day |
| 4th day of life: | 120 – 150 ml per kg body weight per day |
| 5th day of life: | 140 – 160 ml per kg body weight per day |
| 6th day of life: | 140 – 180 ml per kg body weight per day |
| 1st month, prior to establishment of stable growth: | 140 – 170 ml per kg body weight per day |
| 1st month, after establishment of stable growth: | 140 – 160 ml per kg body weight per day |
| 2nd – 12th month of life: | 120 – 150 ml per kg body weight per day |
| 2nd year: | 80 – 120 ml per kg body weight per day |
| 3rd – 5th year: | 80 – 100 ml per kg body weight per day |
| 6th – 12th year: | 60 – 80 ml per kg body weight per day |
| 13th – 18th year: | 50 – 70 ml per kg body weight per day |

*Method of administration*

Intravenous use.

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 is necessary to administer large volumes, further contra-indications 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

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.

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, 5 % w/v Glucose Intravenous Infusion 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, serum electrolytes (especially potassium and sodium) and the acid-base and water balance.

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 solutions should not be administered through the same infusion equipment, simultaneously, before, or after administration of blood, because of the possibility of pseudo-agglutination.

The infusion of hypotonic fluids such as 5 % w/v Glucose Intravenous Infusion 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.

*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 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 doses with respect to reproductive toxicity (see section **5.3**).
5 % w/v Glucose Intravenous Infusion can be used during pregnancy, as long as the blood glucose, electrolyte and fluid balance are carefully controlled and are within the physiologic ranges. 5 % w/v Glucose Intravenous Infusion 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 B. Braun 50 mg/ml no effects on the breast-fed newborns/infants are anticipated.

5 % w/v Glucose Intravenous Infusion can be used during breast-feeding as indicated.

Fertility

No data available.

## 4.7 Effects on ability to drive and use machines

5 % w/v Glucose Intravenous Infusion 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.

## 4.8 Undesirable effects

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

## 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 my 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 Solutions for parenteral nutrition, carbohydrates
ATC code: B05BA03

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 metabolized. 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 re-introduced 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

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

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

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

### 6.3 Shelf life

**Unopened**

3 years

**After first opening the container**

Once containers are opened contents 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 and would normally not be longer than 24 hours at 2 to 8 °C unless dilution / reconstitution has taken place in controlled and validated aseptic conditions.

## 6.4 Special precautions for storage

Do not store above 25°C. 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: 50 ml, 100 ml, 250 ml, 500 ml, 1000 ml
  available in packs of:
  20 × 50 ml, 20 × 100 ml
  10 × 250 ml,
  10 × 500 ml
  10 × 1000 ml

## 6.6 Special precautions for disposal

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 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 5% Glucose Intravenous Infusion has an acidic pH, incompatibilities can occur on mixing with other medicinal products.

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

When adding additives observe usual precautions of asepsis strictly.

## 7 MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen, Germany

Postal address:
34209 Melsungen, Germany

Phone: +49/5661/71-0
Fax: +49/5661/71-4567

## 8 MARKETING AUTHORISATION NUMBER(S)

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03/08/2018