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

The solution contains per	500 ml	1000 ml
Anhydrous Glucose as Glucose Monohydrate	25.0 g	50.0 g

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Infusion.
A clear, colourless, sterile, and non-pyrogenic aqueous solution.

Theoretical osmolarity:	278 mOsm/l
Caloric value	835 kJ/l = 200 kcal/l
Titration acidity (to pH 7):	< 0.5 mmol/l
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

4.2.1 Dosage

The quantity and rate of administration is dependent on the age, weight, clinical state and degree of deficiency of the patient and must be determined on an individual basis.

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.

Maximum daily dose
The maximum daily dose for intravenous fluid administration is 40 ml per kg body weight per day (corresponding to 2 g of glucose per kg body weight per day).

For a 70 kg person this corresponds to a maximum infusion of 140.0 g/d of glucose, respectively 560 kcal. The maximum daily dose is in accordance with usual limitations of the daily fluid intake.

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.

4.2.2 Method and route of administration

For intravenous infusion. Can be administered peripherally if the medicament permits.
See also section 6.6.

4.3 Contraindications

Hyperglycaemia;
Hypokalaemia;
Acidosis.

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

Hyperhydration states;
Hypotonic dehydration if depleted electrolytes are not replaced.

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

4.4.1 Special warnings

It is necessary to monitor the blood glucose concentration.

It is necessary to monitor the fluid balance, serum electrolytes, acid-base status.

In patients with disturbed glucose metabolism, as present e.g. in postoperative or posttraumatic conditions, Glucose Intravenous Infusion BP 5 % w/v must be administered with care, i.e. under blood glucose monitoring, and dosage must be adapted in order to prevent physiological stress. Glucose Intravenous Infusion BP 5 % w/v should be administered with caution in patients with diabetes mellitus.

Glucose Intravenous Infusion BP 5 % w/v must not be administered in the same infusion system as blood products since it can lead to pseudo-agglutination.

4.4.2 Special precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Glucose Intravenous Infusion BP 5 % w/v can be given in these situations if indicated.

4.7 Effects on ability to drive and use machines

This medicinal product has no effect on ability to drive and use machines.

4.8 Undesirable effects

None to be expected if the solution is used according to instructions.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: http://www.hpra.ie/; e-mail: medsafety@hpra.ie

4.9 Overdose

4.9.1 Symptoms

Overdose may lead to hyperhydration, electrolyte and acid-base disturbances, hyperglycaemia, glycosuria, hyperosmolarity, and hyperglycaemic hyperosmotic coma.

4.9.2 Emergency treatment, antidotes

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

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 17 kJ/g or 4 kcal/g.
In adults, the normal concentration of glucose in blood is reported to be 60 – 100 mg/100 ml, or 3.3 – 5.6 mmol/l (fasting).

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.

5.2 Pharmacokinetic properties

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

In glycolysis glucose is metabolised to pyruvate or to lactate. Lactate can be partially re-introduced into the glucose metabolism (Cori cycle). Under aerobic conditions pyruvate is completely oxidised to carbon dioxide and water. The final products of the complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidneys (water).

5.3 Preclinical safety data

No preclinical studies on toxicity and safety pharmacology have been conducted with Glucose Intravenous Infusion BP 5 % w/v.

Since glucose is a natural substrate of human metabolism, Glucose Intravenous Infusion BP 5 % w/v is not expected to have toxic effects when used as directed.

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 medicaments.

Erythrocyte concentrates must not be suspended in Glucose Intravenous Infusion BP 5% w/v because pseudo-agglutination may occur.

Glucose solutions should not be infused through the same equipment as blood, see section 4.4.

6.3 Shelf life

Shelf life of the medicinal product as packaged for sale:
3 years.

Shelf life after first opening the container:
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^{o}C. Store in the original container.

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: 250ml, 500 ml, 1000 ml. In packs of 10.

6.6 Special precautions for disposal and other handling

Single-dose container. After use, the container and any residual content should be discarded.

Solution is to be used immediately after breaking the seal. Partially used containers must not be reconnected.

Only to be used if the solution is clear, free from visible particles and the container or its closure do not show visible signs of damage.

7 MARKETING AUTHORISATION HOLDER

B. Braun Medical Limited
3 Naas Road Industrial Park
Dublin 12
Republic of Ireland.

8 MARKETING AUTHORISATION NUMBER

PA 179/1/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

August 2014