



Summary of Product Characteristics

B. Braun Medical Limited · Dublin 12

Glucose 50 % w/v

Sterile Concentrate, Concentrate for Solution for Infusion

1. Name of the medicinal product

Glucose 50 % w/v Sterile Concentrate, Concentrate for Solution for Infusion

2. Qualitative and quantitative composition

50 ml of solution contain anhydrous glucose 25 g (as glucose monohydrate)

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Concentrate for solution for infusion (sterile concentrate).

Clear, colourless up to faintly straw-coloured solution.

Caloric value: 420 kJ/50 ml 100 kcal/50 ml

Theoretical osmolarity: 2770 mOsm/l

Titration acidity (to pH 7.4) < 1.5 mmol/l

pH 3.5 - 5.5

4. Clinical particulars

4.1. Therapeutic indications

Hypoglycaemia.

4.2. Posology and method of administration

Recommended dosage schedule

The dose is adjusted according to the actual blood glucose concentration.

Method and route of administration

Only diluted, as additive to solutions for intravenous infusion, to avoid vein irritation.

4.3. Contraindications

Hyperglycaemia; Hypokalaemia; Acidosis.

4.4. Special warnings and special precautions for use

Special warnings

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

Special precautions for use

Blood glucose concentrations should be monitored, depending on metabolic conditions and administered dose.

4.5. Interaction with other medicinal products and other forms of interaction

None to be stated.

4.6. Pregnancy and lactation

Glucose 50 % w/v Sterile Concentrate can be administered in these situations as indicated.

4.7. Effects on ability to drive and use machines

Not applicable

4.8. Undesirable effects

As long as the product is used as directed, no undesirable effects are to be expected.

4.9. Overdose

Symptoms

In case of overdose hyperglycaemia and renal glucose losses may occur.

Emergency treatment, antidotes

The manifestations of overdose can be treated by either reducing the dose or giving insulin.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Glucose is utilised as an energy source in the organism.

5.2. Pharmacokinetic properties

Exogenously administered glucose is indiscernably mixed with the body's endogenous substrate pools. Specific pharmacokinetic data are not provided.

5.3. Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those already stated in other sections of the SPC.

6. Pharmaceutical Particulars

6.1. List of excipients

Water for injections

6.2. Incompatibilities

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

6.3. Shelf Life

Unopened: 3 years.

Once opened, the product should be used immediately.

6.4. Special precautions for storage

Do not store above 25 °C.

6.5. Nature and contents of container

Glass vials sealed with rubber stoppers. Contents: 50 ml, 20 x 50 ml

6.6. Special precautions for disposal and other handling

Single-dose container. Discard unused contents. Only to be used if solution is clear and the container or its closure do not show visible signs of damage. Only to be used diluted, as an additive to solutions for intravenous infusion, to avoid vein irritation.

7. Marketing authorisation holder

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

8. Marketing authorisation number

PA 179/1/39

9. Date of the first authorisation/renewal of the authorisation

Date of the first authorization: 17 August 1992

Date of last renewal: 17 August 2002

10. Date of revision of the text

June 2007



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B. Braun Medical Limited
Dublin 12



**Patient Information Leaflet****Read carefully**

B. Braun Medical Limited · Dublin 12

Glucose 50 % w/v

Sterile Concentrate, Concentrate for Solution for Infusion

Please read this leaflet carefully if you have been or will be given Glucose 50 % w/v Sterile Concentrate. Don't throw this leaflet away. You might want to read it again while you are receiving your treatment.

This leaflet has been prepared to give you some information about this medicine. However, this leaflet cannot tell you everything about your medicine. So, if you have any questions please ask your doctor or pharmacist.

What is in this medicine?

The name of this medicine is Glucose 50 % w/v Sterile Concentrate, Concentrate for Solution for Infusion

- Each 10 ml of medicine contains anhydrous glucose 5 g as Glucose Monohydrate, and Water for Injections.
- Your medicine is supplied as a concentrate for solution for infusion in glass vials containing 50 ml of liquid.
- Glucose 50 % w/v Sterile Concentrate is used to treat low blood glucose levels (hypoglycaemia).

Who makes this medicine?

PA Holder:

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

PA Number:

PA 179/1/39

Manufacturer:

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

What does this medicine do?

Glucose can be used to treat hypoglycaemia, low blood sugar levels.

Are there any patients who should not be given this medicine?

This medicine should not be given if you have been told that you have any of the conditions below:

- A high blood sugar level (hyperglycaemia).
- A low blood potassium level (hypokalaemia).
- Acidosis - a condition in which certain body fluids are more acidic than they should be.

Extra care may be needed in some conditions.

Tell your doctor if you suffer from any of the following, as your medicine may need to be changed or adjusted:

- Diabetes
- Conditions requiring blood transfusions

Your doctor may also need to monitor your blood levels of glucose by means of blood tests.

How is this medicine given?

Glucose 50 % w/v Sterile Concentrate will be given to you, probably by a healthcare professional, normally by Injection. This means that your medicine is administered directly into your vein. It will normally be diluted before use.

The amount of the injection that you will receive, will depend upon your actual blood glucose concentration.

What if you are given too much?

- If you think you have been given too much of this medicine then you should consult your doctor.

Overdose can lead to:

- Raised blood sugar
- Sugar in the urine

Unwanted effects?

- No side effects are expected from Glucose 50 % w/v Sterile Concentrate when it is used as directed.

- If you experience any effect that troubles you, you should consult your doctor.

How should this medicine be kept?

Normally a health professional will look after your medicine for you.

- This medicine should be kept in a safe place where children cannot see or reach it.
- This medicine should be stored in its original container. Do not store above 25 °C.
- This medicine should not be used unless the solution is clear and the container undamaged.
- The use before date shown on the container should be checked at the time of receipt. Only product which is "in date" should be used.

Further Information

- This medicine has been prescribed only for you.
- You should never give it to anyone else.
- Further information is available from your doctor and pharmacist.

Date of preparation

June 2007

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