SmPC

Country:	Lebanon
Date of approval:	22.06.2009
Procedure:	National

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GLUCOSE PROAMP 30% AGUETTANT, solution for infusion

2. 2- QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose, anhydrous ……..30 g
as glucose, monohydrate

for 100 ml of infusion solution

One 10 ml ampoule contains 3 g of anhydrous glucose.

osmolarity: 166.5 mOsm/100 ml
Carbohydrate calories: 1200 Kcal/l
The pH of the solution is between 3.5 and 5.0
A list of excipients is provided in section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.
Clear solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is indicated for the emergency treatment of severe hypoglycaemia.

4.2 Posology and method of administration

Peripheral intravenous infusion only.
The dosage should be adjusted depending on the clinical condition, weight and nutrition status of the patient and any other concomitant medications administered.

4.3 Contraindications

This medicine must not be given in case of hyperhydration and glucose intolerance.

4.4 Special warnings and precautions for use

Special warnings:

GLUCOSE PROAMP 30% is a hypertonic solution. It must be administered in a slow infusion.

Precautions for use:

- Patients must be clinically monitored and laboratory tests monitoring the salt and water balance, blood and urine glucose levels and serum ketones and potassium should also be performed.
- Where necessary, parenteral potassium and/or insulin supplements may be given..
- Monitor blood and urine glucose in diabetic patients and adjust the insulin dose where necessary.
- Glucose infusions should not be administered through the same infusion kit and at the same time as blood owing to the risk of pseudo-agglutination.
- Ensure that any other medicines to be added are compatible both with the container and its contents. Also refer to the information leaflet supplied with the medicinal product to be added. If another medicine is added into the infusion, the resulting solution must be administered immediately.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Pregnancy and lactation

This medicine may be administered to pregnant women and nursing mothers if required.

4.7 Effects on ability to drive and use machines
Not applicable.

4.8 Undesirable effects
The possible side effects are:

- hyperglycaemia
- risk of tissue necrosis in the event of extravasation,
- polyuria induced by glucose
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4.9. Overdose
Overdose may cause the following: hyperosmolarity, dehydration, hyperglycaemia, hyperglycosuria and osmotic diuresis. Treatment is symptomatic.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS / CARBOHYDRATES
ATC code: B05BA03
(B: blood and blood-forming organs).

Hypertonic glucose solution
10 ml of the solution provides 12 kcal.
This medicinal product has the pharmacological properties of glucose.
5.2 Pharmacokinetic properties
This medicinal product has the pharmacological properties of glucose.
5.3 Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS
6.1. List of excipients
Water for injections

6.2 Incompatibilities
Make sure that the solution has not changed colour and/or that it does not contain any precipitate, insoluble complex or crystals.
Before adding any other medicinal product into the solution, make sure that its efficacy is not impaired by the pH of 30% glucose solution.
If another medicine is added into the 30% glucose solution, the resulting mixture must be administered immediately.

6.3 Shelf-life
2 years.
6.4 Special precautions for storage
Store below 25°C .

6.5. Nature and contents of the container
10 ml (polypropylene) ampoules, box of 10, 20, 50 or 100 ampoules

6.6 Instructions for use and handling
No particular requirements.