PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

GLUKOZE

Solution for injection – 4000 mg / 10 ml (40%)

Solution for infusion – 5%

(Glucose)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. WHAT GLUKOZE IS AND WHAT IT IS USED FOR

Glucose is a monosaccharide, which by mouth, but mainly parenterally, is used as a source of energy; it takes part in the metabolism of lipids and prevents acidosis by increasing the hepatic nitrogen content. The latter function has been used to prevent and to treat intoxications from medicines which are hepatotoxic. In absence of a sufficient quantity of glucose, lipids are highly oxidized and the intermediate products, such as: hydroxybutyric acid and acetoacetic acid are accumulated in blood becoming a potential cause for ketoacidosis.

It is indicated for fluid replacement and to provide the necessary energy, as a parenteral nutrition

of severely-ill patients, in hypoglycaemia; in intoxications with different substances (barbiturates, morphine, salicylates, mercuric compounds).

2. BEFORE YOU TAKE GLUKOZE

Do not take Glukoze:

- if you are hypersensitive to any of the ingredients of the solution;
- if you have diabetes mellitus;
- if you have severe renal failure.

Hypertonic solutions of glucose (e.g. 40 %) are contraindicated in:

- anuria;
- intracranial or intraspinal haemorrhagia;
- delirium tremens when dehydration is present.

Warnings and precautions

Talk to your doctor before taking Glukoze. Glucose should be administered very cautiously to patients with intollerance of any nature to glucose.

Special caution is required in patients with heart failure and in clinical conditions associated with edemas and hydrosaline retention.

Special caution is required when administering glucose to patients receiving corticosteroids or corticotropine.

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 (antidiuretic hormone) agonist drugs are at particular risk of acute hyponatremia (low level of sodium in the blood) upon infusion of glucose, that may lead to encephalopathy (brain edema) characterized by: headache, nausea, seizures, lethargy, vomiting.

Children, women of childbearing potential and patients with serious brain conditions like meningitis (infection of the membranes surrounding the brain) or brain injury (like intracranial bleeding) are at particular risk of severe and life-threatening brain swelling caused by an acute decrease in blood sodium levels.

The concentrated solutions of glucose (40 %) should be used with special caution in advanced

cerebral sclerosis.
Glucose solutions should not be given through the same infusion equipment as whole blood as haemolysis and clumping can occur.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Special care is recommended if you are taking any of the following drugs during glucose treatment:

- corticosteroids or corticotropin;
- drugs that increase the effect of vasopressin:
  - 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 hyponatremia also include diuretics in general and antiepileptics such as oxcarbazepine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
There are no adequate data on the use of glucose in pregnant women. However it should be administered with caution in pregnant women especially during labour, particularly if administered in combination with oxytocin due to the risk of hyponatremia.

3. HOW TO TAKE GLUKOZE

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you feel that the effects of glucose are too strong or too weak, talk to your doctor or pharmacist.

The dose will be decided based on the patient characteristics (age, weight, clinical conditions, hydro-electrolyte balance and acid-base balance). Monitoring these balances may be necessary before and during administration, especially in patients with increased non-osmotic vasopressin release or in patients taking vasopressin agonist medicines, due to the risk of hyponatraemia. Monitoring of serum sodium is particularly important.

If you take more Glukoze than you should

If you take more Glukoze than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

Prolonged or rapid infusion of large volumes of iso-osmotic solutions (5%) may cause oedema or water intoxication; conversely, prolonged or rapid use of hyperosmotic solutions may result in dehydration as a consequence of the induced hyperglycaemia.

If you forget to take Glukoze

If you forget a dose (or more), take the next dose in its usual time.

Do not take a double dose (or higher) to make up for a forgotten dose(s).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, glucose can cause side effects, although not everybody gets them.

Most of the side effects are dose-related and disappear when the dose is reduced or the tratment is stopped. Some of them may occur in the begining of the treatment and then disappear spontaneously during the treatment.

Intravenous glucose solutions, particularly hyperosmotic solutions (e.g. 40%), may cause local pain, vein irritation, and thrombophlebitis. Some of these reactions may be due to degradation products present after autoclaving or to poor technique in giving the solution. Intravenous infusion (5% solution) can lead to fluid and electrolyte disturbances including hypokalaemia, hypomagnesaemia, hypophosphataemia and hyponatremia. The last one may cause irreversible brain damage and death due to the development of acute hyponatraemic encephalopathy.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE GLUKOZE

Keep this medicine out of the sight and reach of children!

Do not use this medicine after the expiry date which is stated on the packaging.

Do not store above 25°C!

6. OTHER INFORMATION

What Glukoze contains

The **active substance** is glucose monohydrate or glucose anhydrous.

Glukoze 40% solution for injection:

Each 10 ml ampoule contains glucose monohydrate equivalent to 4000 mg anhydrous glucose.

The **excipients** are: sodium chloride, hydrochloric acid and water for injections.

Glukoze 5% solution for infusion

1 ml solution for infusion contains glucose monohydrate equivalent to 50 mg glucose anhydrous.

The **excipient** is water for injections.

Contents of the pack

Solution for injection 40%: box with 10 ampoules.

Solution for infusion 5%: graduated glass bottles or plastic bags with 250 ml or 500 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in January 2024.