Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Glycophos®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you given Glycophos® against any benefits they expect it will have for you.

Please read this leaflet carefully. If you have any questions or are unsure about anything, please ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What is Glycophos® used for

Glycophos® is a sterile concentrate solution which provides the body with phosphate by the intravenous route. It can be used in adults and children. When the intake of nutrients or food into the mouth or directly into the gut is not possible, or it is not enough to supply the body's needs, then intravenous nutrients or foods can be given. This is especially important for people whose bodies are under physical stress from illness or recent surgery. During illness or after surgery the body requires nutrition or food.

It is usually given together with fats, amino acids, glucose and vitamins to provide a complete intravenous diet.

Before you are given Glycophos®

You must NOT use this product:

- if you are allergic (hypersensitive) to any of the ingredients of Glycophos®
- if you are suffering from dehydration
- if you have high phosphate levels in the blood
- if you have high sodium levels in the blood
- if you have serious kidney disease without access to dialysis
- if you are in acute shock
- if you are in an unstable condition, such as after serious trauma, uncontrolled diabetes, acute heart attack, stroke, blood clot, metabolic acidosis (a disturbance resulting in too much acid in the blood), serious infection (severe sepsis), coma and if you don't have enough body fluid (hypotonic dehydration).

Special care has to be taken while this product is given to you. Tell your doctor if you have:

kidney problems

If during the infusion you get fever, rash, swelling, difficulty in breathing, chills, sweating, nausea or vomiting, tell the health care professional immediately because these symptoms might be caused by an allergic reaction or that you have been given too much of the medicine.

Your doctor may regularly need to check your blood for liver function tests and other values.

Please tell your doctor if you have recently taken some medicines, even without prescription.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Glycophos® should only be given to pregnant or breast-feeding women if the doctor finds it necessary.

How Glycophos® is given

How much will be given

Your doctor will decide on the dose for you individually depending on your body weight and function. Glycophos® will be given to you by a health care professional.

How is it given

Glycophos® is usually mixed in the bag of amino acids, glucose and/or fats, vitamins and given as a continuous infusion into a central vein. An electronic pump may be used to control the speed of the infusion.

If you are given too much (overdose)

This rarely happens as Glycophos® is usually administered under the care of a trained health care professional in a hospital or clinic setting.

If you have any concerns immediately telephone your doctor or contact the Poisons Information Centre (Australia: 13 11 26).

Side Effects

Like all medicines, Glycophos® can cause side effects, although not everybody gets them. No known undesirable effects have been reported with the use of Glycophos® according to the recommendation.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- · nausea and vomiting
- flatulence
- · abdominal pain
- swelling of hands, ankles or feet
- · fast heart beat
- · difficulty in breathing
- · lack of appetite
- low or high blood pressure
- · slight increase in body temperature
- chills
- dizziness
- headaches
- hypersensitivity reactions (skin rash)
- sensations of hot and cold
- pain in the neck, back, bones, chest
- paleness.

If any of these side effects occurs, or if you notice any side effects not listed in this leaflet, please contact your doctor or a pharmacist.

Storage

Glycophos® should be stored below 25°C. As with any medicine, Glycophos® should be stored out of the reach of children.

The contents of each vial of Glycophos® is for single use in one patient only. Any unused Glycophos® should be discarded.

The expiry date of Glycophos® is on the label of the pack. Glycophos® should not be used if the expiry date has passed.

Product Description

What it looks like

Glycophos® Concentrated injection solution for infusion is a sterile, clear, colourless solution essentially free from visible particles which is supplied in 20 mL plastic ampoules. It is for addition to infusion solutions.

Ingredients

Each 1 mL of Glycophos® contains 306.1 mg of sodium glycerophosphate hydrate equivalent to 216 mg of sodium glycerophosphate.

Each 1 mL of Glycophos® corresponds to 1 mmol of glycerophosphate and 2 mmol of sodium

Glycophos® also contains the excipients hydrochloric acid and water for injections.

It does not contain any preservative.

Osmolality: 2760 mOsm/kg water pH: 7.4 Glycophos® does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Pack size

Box of 20 x 20 mL ampoules AUST R 312021

Further Information

More detailed information is available from your doctor or pharmacist. Therefore, if you have any concerns about the information or about Glycophos®, please ask your doctor or pharmacist.

Sponsor

Fresenius Kabi Australia Pty Ltd. Level 2, 2 Woodland Way Mount Kuring-gai, NSW 2080 Australia.

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