Package leaflet: Information for the patient **Glyssogel Sterile Gel**

Glycerine 10%

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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. See section 4.

What is in this leaflet

- 1. What Glyssogel is and what it is used for
- What you need to know before you use Glyssogel
- 3. How to use Glyssogel
- 4. Possible side effects
- 5. How to store Glyssogel
- 6. Contents of the pack and other information

What Glyssogel is and what is used for

Glyssogel is a personal lubricant that is usually used as a lubricant for sexual intercourse. Unlike petroleum or oil-based lubricants, it does not react with latex condoms or diaphragms. Glyssogel is also used as a substitute for ultrasound gel, to aid insertion of suppositories or tampons, during medical examinations, or for other reasons.

Important Information

Follow all directions on the label and packaging. Tell all your healthcare providers about all your medical conditions, allergies, and all the medicines you use.

2. What you need to know before you use Glyssogel

You should not use Glyssogel if you are allergic to it. Glyssogel will not prevent sexually transmitted infections (STIs) or reduce the risk of pregnancy.

Ingredients such as methylparaben (contained in Glyssogel) may cause skin irritations in some people.

Ask a doctor or pharmacist if it is safe for you to use Glyssogel if you:

- have any type of allergy
- have any cuts, irritation, sores, or wounds near your genital area or near the area where you plan to use Glyssogel
- are pregnant or breastfeeding
- have a sexually transmitted infection (also called a sexually transmitted disease or STD).

What other drugs will affect Glyssogel?

• Glyssogel, which is applied topically, is unlikely to interact with drugs that you take orally. However, it may alter the effect of other topical agents which are applied to the same area. Tell each of your health care providers about all medicines you use, including prescription and over-the-counter medicines, vitamins, and herbal products.

- Glyssogel is safe to use with latex and polyisoprene condoms, diaphragms and silicone.
- Remember to keep Glyssogel and all other medicines out of the reach of children, never share your medicines with others, and to use this medication only for the indication prescribed.

 Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

3. How to use Glyssogel

Use exactly as directed on the label, or as prescribed by your doctor.

Apply the desired amount of lubricant directly from the tube to the skin or to a condom. Reapply as required.

If skin, penile, or vaginal irritation develops, stop using Glyssogel immediately and wash the area with water. Seek medical attention if the irritation persists.

Glyssogel should not be ingested or allowed to come into contact with the eyes.

In case of accidental ingestion, rinse out the mouth with water. Do not induce vomiting. Seek medical attention if adverse health effects persist.

In case of eye contact, rinse immediately with water and seek medical attention if eye irritation persists.

Keep the tube tightly closed and sealed when not in use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Dispose of carefully to avoid environmental contamination.

What happens if I miss a dose?

Glyssogel can be used as needed and does not have a daily dosing schedule. Seek advice from your pharmacist or doctor if the lubricating effects of Glyssogel are not sufficient for your needs.

What happens if I overdose?

Rinse out your mouth with water if you accidentally ingest Glyssogel and seek medical attention if adverse effects persist. In case of skin irritation, wash the area with water and discontinue use. Seek medical attention if the skin irritation persists.

What should I avoid while using Glyssogel

Avoid getting Glyssogel in your eyes, nose, or mouth. If this does happen, rinse with water.

4. Possible side effects

Get emergency medical help if you have any of these signs of a severe allergic reaction when using Glyssogel: hives, difficulty breathing, and swelling of your face, lips, tongue, or throat. Stop using Glyssogel and rinse the affected area with water if you develop severe burning, stinging, redness, or irritation where the product was applied. Call your doctor if the irritation



persists.

Stop using Glyssogel if you develop vaginal thrush (candida) after using the product. For some women, the glycerol contained in Glyssogel can trigger such infections. Seek treatment for the vaginal thrush from a pharmacist or doctor and talk to them about alternative lubricants. Glyssogel is greaseless, non-irritating gel.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

5. How to store Glyssogel

- 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 tube and the outer packaging. The expiry date refers to the last day of that month. - Do not store above 30°C. Keep away from humidity.

- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information What Glyssogel contains

The active substance in Glyssogel is Glycerin. Each gram contains 100 mg of glycerin. The other ingredients are Ethanol, Propylene glycol, Methyl paraben, Carbopol, Sodium hydroxide and Water.

Ethanol may cause burning sensation on damaged skin.

Propylen glycol may cause skin irritation.

Methyl paraben may cause allergic reactions (possibly delayed).

What Glyssogel looks like and contents of the pack

Glyssogel is a transparent, sterile gel. Available in tubes of 80 grams packed in a carton box.

Marketing Authorisation Holder and Manufacturer

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