

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

EZ Lubricating Jelly

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Glycerin BP	11.25 % w/w
Methyl Paraben BP	0.1 % w/w
Propyl Paraben BP (as preservatives)	0.04 % w/w

3. PHARMACEUTICAL FORM

Gel-External preparation.
A clear transparent gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The ideal all-round lubricant. A widely used lubricating jelly in gynecological and hospital procedure. Excellent for easy insertion of catheters, scopes, rectals, thermometers, enemas, douches and similar types of nozzles.

4.2 Dosage and Method of Administration

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

4.3 Contraindications

Sensitivity to glycerol and other ingredients used in the formulation.

4.4 Special warnings and precautions for use

Warnings:

1. Use of personal lubricants that contains glycerol may trigger yeast infection in women who are prone to them.
2. Ingredients such as methyl paraben and propyl paraben may cause irritation in some people.
3. Ask a doctor or a pharmacist if it is safe for you to use EZ jelly if you:
 - a. have any type of allergy
 - b. have any type cuts, irritation, sores or wounds near your genital area or near the area where you plan to use EZ jelly.
 - c. are pregnant or breastfeeding
 - d. have a sexually transmitted infection.

Precautions

1. Apply EZ LUBRICATING JELLY to gloves or instrument in sufficient quantity to form a film over the area which is to come into contact with the patient. Wash off after use Reapply as required.
2. If skin, penile, or vaginal irritation develops, stop using Jelly immediately and wash the area with water. Seek medical attention if the irritation persists.
3. EZ Jelly should not be ingested or allowed to come into contact with the eyes.
4. In case of accidental ingestion, rinse out the mouth with water. Do not induce vomiting. Seek medical attention if adverse health effects persist.
5. In case of eye contact, rinse immediately with water and seek medical attention if eye irritation persists.
6. Keep tightly closed under normal room temperature (15-30)°C in a dry place. Protect from light. Protect from light. Replace cap after use.
7. If container is damaged or opened, sterility is not guaranteed.

4.5 Interaction with other medicinal products and other forms of interaction

EZ Lubricating Jelly, 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.

Remember to keep EZ Jelly 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

4.6 Fertility, pregnancy and lactation

- a. You should not use EZ lubricating jelly if you are allergic to it. EZ jelly will not prevent risk of Sexually Transmitted Infections (STIs) or reduce the risk of pregnancy
- b. Ask a doctor or a pharmacist if it is safe for you to use EZ lubricating jelly, if patients are pregnant or breastfeeding.

4.7 Effects on ability to drive and use machines

Not Reported

4.8 Undesirable effects

Get emergency medical help if you have any of these signs of a severe allergic reaction when using EZ Jelly: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Stop using EZ Jelly 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 EZ jelly if you develop vaginal thrush (candida) after using the product. For some women, the glycerol contained in EZ jelly can trigger such infections. Seek treatment for the vaginal thrush from a pharmacist or doctor and talk to them about alternative lubricants. EZ Jelly is odorless, colorless, and alcohol-free.

4.9 Overdose

Rinse out your mouth with water if you accidentally ingest EZ Jelly 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.

5. PHARMACOLOGICAL PROPERTIES

EZ jelly has no pharmacological or Therapeutic action .It is used as the ideal all around lubricant. A widely used lubricating jelly in gynaecological and hospital procedure. Excellent for easy insertion of catheters, scopes, rectals, thermometers, enemas, docuhes and similar types of nozzles.

EZ lubricating jelly is greaseless, water soluble and non irritating, safe ideal for general lubricating needs.

Its main lubricating ingredients are glycerol (glycerin). It contains Methyl Paraben and Propyl Paraben as antimicrobial preservative, Disodium EDTA acts as chelating agent and Carbomer acts as jelling agent. Sodium hydroxide adjust the p H and Water acts as Vehicle.

Preclinical safety data

Not known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Paraben, Propyl Paraben, Disodium Edetate, Carbomer , Sodium Hydroxide & Purified water .

6.2 Incompatibilities

Not known

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Keep tightly closed under normal room temperature (15 - 30°C) in a dry place.
Protect from light.Do not freeze. Keep out of reach of children. Replace cap after use.

6.5 Nature and contents of container and special equipment for use, administration or implantation

Printed aluminium collapsible tube containing either 30 gram or 50 gram or 82 gram

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORISATION HOLDER

Ciron Drugs & Pharmaceuticals Pvt. Ltd.
C- 1101 /1102, Lotus Corporate Park, Graham Firth Steel Compound,
Jay Coach Junction, Western Express Highway, Goregaon (East)
Mumbai- 400 063, India.

8. MARKETING AUTHORISATION NUMBER(S)

00471/00531/NMDR/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02.12.2020

10. DATE OF REVISION OF THE TEXT

14/07/2023

11. Reference

<https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=2a9a3aba-d3e0-4fd2-a3f7-535d25fba4eb>