

episil[®] ORAL LIQUID

Package leaflet: Information for the user

Read this entire leaflet carefully because it contains important information for you. You should use episil[®] carefully and according to instructions given to obtain the best results.

- Keep this leaflet. You may need to read it again.
- Contact your doctor or pharmacist if you need more information or advice.
- If you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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1 Description

episil[®] is a lipid based oral liquid in a multi-dose container. episil[®] gives relief of pain via mechanical action by a protective film that forms in the oral cavity and adheres to the oral mucosa.

2 Indications for use

episil[®] has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including Oral Mucositis/Stomatitis (may be caused by chemo therapy or radio therapy).

3 Contraindications

Do not use episil[®] if you are: allergic (hypersensitive)

- to any of the ingredients,
- to peanuts or soya,
- to peppermint oil.

4 Precautions

episil[®] contains a small amount of ethanol (alcohol), less than 100 mg per dose, which may cause a burning sensation when applied to sore mucosal surfaces.

episil[®] contains a small amount of ethanol (alcohol); if you should be accident swallow the whole content of a bottle you may be affected.

episil[®] contains propylene glycol which may cause skin irritation and peppermint oil which may cause allergic reaction.

5 How to use episil[®]

Instructions for use: Remove the protective cap from the metering pump. Prime the pump mechanism prior to the first dose by pumping into a paper cloth until an even liquid stream occurs. Firmly press the pump and apply the liquid stream to the oral cavity 1-3 times. Distribute to affected areas in the mouth and wait a few minutes for the liquid to gel and protective film to form. episil[®] is intended for use in the oral cavity as far as the pharynx. Do not swallow.

Dosing: Firmly press the pump and apply the stream to the oral cavity 1-3 times. Use 2-3 times per day or as needed.

Duration of treatment: episil[®] is normally intended for continuous use for not more than 30 days.

6 Adverse reactions

None known.

7 How to store episil[®]

- Keep out of the reach and sight of children.
- Do not use after the expiry date which is stated on the bottle after abbreviation Exp.
- Use within one month of first use.
- Each bottle should be used by one person only.
- Store the bottle in the outer carton and at room temperature.

8 Further information/How supplied

Content: Glycerol dioleate, soy phosphatidylcholine (lecithin), ethanol, propylene glycol, polysorbate 80, peppermint oil.

Each amber glass bottle contains 10 mL of episil[®] and provides 65 applications.

Caution: Federal law restricts this device to sale by or on the order of a physician.

For additional information about episil[®]:

Visit: episilusa.com

Contact: **844-586-8953**