

episil[®] ORAL LIQUID

Information for the user

Please read this entire leaflet before you start using episil[®] oral liquid because it contains important information. Use the product according to the instructions provided in this leaflet in order to obtain the best results.

- Keep this leaflet, as you may need to read it again.
- Ask your pharmacist or doctor if you need more information or advice.

This leaflet contains the following information:

1. Product description
2. Intended use
3. Before you use episil[®] oral liquid
4. How to use episil[®] oral liquid
5. Possible side effects
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1 Product description

episil[®] oral liquid is a lipid-based, preservative-free fluid supplied in a multi-dose container. episil[®] liquid provides relief of pain by a protective film that forms within 5 minutes in the oral cavity (mouth) and adheres to the oral mucosa. The extent of pain relief, as well as the feel of the lipid film formed in the mouth, may vary over time and will also depend on the oral status.

2 Intended use

episil[®] oral liquid is intended for the management and relief of pain in the oral cavity, soothing lesions of various origins. It can also be used for preventing the risk of painful and inflammatory conditions of the mouth such as oral mucositis/stomatitis, which may be caused by chemotherapy and/or radiotherapy.

3 Before you use episil[®] oral liquid

Do not use episil[®] oral liquid if you are allergic (hypersensitive) to any of the ingredients listed.

Pregnancy and breastfeeding: There are no known concerns with the use of episil[®] liquid during pregnancy or when breastfeeding.

Driving and using machinery: episil[®] liquid has no influence on the ability to drive or use machinery.

Important information about some of the ingredients: episil[®] liquid contains small amounts of ethanol (alcohol), less than 100 mg per dose, which may cause a temporary burning sensation when applied to sore mucosal surfaces. It also contains propylene glycol (may cause skin irritation), soy lecithin and peppermint oil (may cause allergic reaction).

4 How to use episil[®] oral liquid

Instructions for use: Remove the protective cap from the metering pump. Prior to the first use, prime the pump mechanism by firmly pumping into a paper tissue until an even stream of liquid is delivered. If there is an excess of mucus present or pronounced dryness (xerostomia) in the

mouth, then rinsing the mouth with water before using episil[®] oral liquid is recommended. Each bottle should be used by one person only.

Dosage: *Adults (above 18 years of age):* Firmly press the pump and apply the stream of liquid to the oral cavity 1-3 times. Distribute to affected areas in the mouth, for example by using the tongue. In case other means of distribution are used, please take precautions to avoid contamination. The stream can be directed at especially sore areas. The protective film will form within a few minutes. episil[®] liquid is intended for use in the oral cavity (mouth), as far as the pharynx, and is harmless if ingested.

Children and adolescents (below 18 years of age): Apply as for adults (see above). As children generally have a smaller oral cavity (mouth), the dose may need to be adjusted. Start with the lowest dose (i.e. press the pump once) and increase as needed. Use of episil[®] liquid in children should be done under the supervision of an adult.

Frequency of administration: Use 2–3 times per day or as needed.

Duration of treatment: episil[®] liquid is intended for continuous use for up to 30 days.

5 Possible side effects

episil[®] oral liquid has no known side effects. If you notice any side effects, discontinue the treatment immediately and contact your doctor, pharmacist or prescriber.

6 Clinical data

Clinical trials in patients with cancer experiencing oral mucositis have demonstrated strong bioadhesion of the lipid film to the oromucosal surfaces after administration of episil[®] oral liquid. The lipid film protects the affected surfaces and decreases the pain by an average of 40%. A long-lasting effect of up to 8 hours has also been demonstrated. Clinical data show that preventive treatment with episil[®] liquid may reduce the symptoms of oral mucositis caused by intensive chemotherapy.

7 How to store episil[®] oral liquid

Keep out of reach and sight of children. Store the bottle in the outer carton at room temperature. Do not use after the expiration date. episil[®] oral liquid 10 ml should be used within 3 months after first application.

episil[®] liquid should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of a medical device product that is no longer used. These measures will help to protect the environment.

8 Further information

Content: Glycerol dioleate, phosphatidylcholine (*soy lecithin*), ethanol, propylene glycol, polysorbate 80, peppermint oil. Each carton contains an amber glass bottle fitted with a manual metering pump (0.15 ml per pump stroke).

Package size: 10 ml