For the management of oral mucositis pain

Oral mucositis is a serious complication of cancer therapies

Oral mucositis (OM) is one of the most common and debilitating side effects of cancer therapies.¹

**Risk of OM by cancer therapy**

<table>
<thead>
<tr>
<th>Cancer Therapy</th>
<th>Risk of OM</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-dose radiotherapy (HNC)</td>
<td>up to 100%²</td>
</tr>
<tr>
<td>High-dose chemotherapy (BMT)</td>
<td>up to 100%³</td>
</tr>
<tr>
<td>Standard chemotherapy</td>
<td>up to 75%⁴⁻⁵</td>
</tr>
</tbody>
</table>

HNC, head and neck cancers; BMT, bone marrow transplant

**Risk of OM by selected targeted therapy**

<table>
<thead>
<tr>
<th>Targeted Therapy</th>
<th>Risk of OM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Everolimus</td>
<td>up to 78%⁶</td>
</tr>
<tr>
<td>Afatinib</td>
<td>71%⁷</td>
</tr>
<tr>
<td>Sunitinib</td>
<td>up to 29%⁸</td>
</tr>
</tbody>
</table>

**episil® oral liquid — for the management of oral mucositis pain**

episil® oral liquid was developed in Sweden based on the award-winning FluidCrystal® technology. The product contains a patented mixture of phospholipids and glycerol dioleate.⁹ Within minutes of administration, and in contact with only small quantities of saliva, the lipid mixture self-assembles into a protective film that strongly adheres to the oral mucosa.¹⁰ Without producing a numbing effect, episil® oral liquid soothes painful oral lesions.

**episil® oral liquid — advantages**

- Starts working within 5 minutes¹¹⁻¹²
- 40% mean reduction in pain¹³
- Long-lasting effect for up to 8 hours¹¹
- No mixing, gargling or rinsing required¹⁴
- Won’t make your mouth feel numb¹⁴
- Can eat within minutes¹¹

**Indication**

episil® oral liquid 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 chemotherapy or radiotherapy).

**episil® oral liquid safety information**

episil® oral liquid contains a small amount of ethanol (alcohol), which may cause a burning sensation to the sore mucosal surfaces; if you should accidentally swallow the whole contents of the bottle, you may be affected. The propylene glycol in episil® oral liquid may cause skin irritation.

Please see accompanying full Prescribing Information.
episil® Direct program

R-Pharm US, the distributor of episil® oral liquid, has partnered with Cardinal Health Specialty Pharmacy to create the episil® Direct pharmacy program.

Support for patients
- Home delivery of episil® oral liquid
- Education and instructions for use
- Patient outreach to confirm receipt
- Co-pay program automatically applied by episil® Direct
  - Patients with commercial insurance will pay a maximum of $40 per prescription
- For patients who are uninsured or whose insurance does not cover episil® oral liquid, patient assistance is available

Support for healthcare providers
- Payer claim adjudication
- Registered pharmacist available for 24-hour pharmacy support

episil® Direct ordering

- episil® oral liquid prescriptions received by 100 PM ET (with no additional information needed) will be processed and shipped the same day
- If additional insurance information is required, a Cardinal Health Specialty Pharmacy licensed pharmacy technician will:
  - Collect the additional information
  - Follow up with your office and the patient as needed for approval
  - Notify the patient and deliver episil® oral liquid directly to the patient’s home within 24 hours of approval

Call 1-888-662-6779 and a licensed pharmacy technician will collect the necessary patient information.

Fax a prescription on the customized episil® Direct order form to 1-877-800-4790.

Select Cardinal Health Specialty Pharmacy in your eScribe system, and send electronically. If you need help locating Cardinal Health Specialty Pharmacy, please contact your system administrator.

episil® Direct support line

Questions regarding an episil® oral liquid prescription

The episil® Direct support line is available to healthcare providers and patients:

- Call 1-888-662-6779
- Monday-Friday 8:00 AM to 8:00 PM ET
- Registered pharmacist available for 24-hour pharmacy support
- For general inquiries, please e-mail InfoCHSPRx@cardinalhealth.com

References


Please see accompanying full Prescribing Information.

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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:
1. Description
2. Indications for use
3. Contraindications
4. Precautions
5. How to use episil®
6. Adverse reactions
7. How to store episil®
8. Further Information/How Supplied

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 by 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