For the management of oral mucositis pain

Information for healthcare professionals
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
Efficacy proven in clinical studies
In a multicenter, randomized, double-blind, crossover, single-dose trial with 38 head and neck cancer patients undergoing radiotherapy, and with oral mucositis Grades 2–3 (World Health Organization scale), episil® oral liquid provided a long-lasting reduction of intraoral pain for up to 8 hours. The effect was clinically proven with a 40% mean reduction in pain (Likert scale).

Demonstrated safety
episil® oral liquid was well tolerated and had no reported side effects in clinical studies.

Convenient and ready to use
episil® oral liquid is supplied in a convenient, pocket-sized, multidose pump device. It is ready to use and can be applied just before meals.

Recommended dose: 1–3 pump strokes, 2–3 times per day or as needed. episil® oral liquid is intended for continuous use up to 30 days.

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

Do not use episil® oral liquid in patients who are allergic (hypersensitive) to any of the ingredients or to peanuts, soy or peppermint oil.

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.

References
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 1:00 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

Please see accompanying full Prescribing Information.
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, soya phosphatidylcholine (lecithin), ethanol, propylene glycol, polyisorbate 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

Manufacturer:
Camurus AB, Sölvegatan 41 A, 223 70 Lund, Sweden

RX Only

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ORAL LIQUID