

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Eludril™ (mouthwash) (Chlorhexidine digluconate 0.1%, Chlorobutanol 0.5%)**

**Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to use Eludril carefully to get the best results from it.**

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms persist or worsen.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

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### **1. What Eludril is and what it is used for**

Eludril mouthwash is an antibacterial solution which inhibits dental plaque formation.

Eludril is used as an aid in the treatment and prevention of gum inflammation and maintaining good oral hygiene. It is effective in situations where toothbrushing is difficult, for example following oral surgery or in patients with disabilities.

Eludril mouthwash is also suitable in the management of common mouth ulcers and oral candidal infections (fungus infection) and may be used as an add on treatment for minor infections of the throat.

Eludril can also be used as a disinfectant for the cleansing of removable dentures.

### **2. Before you use Eludril**

#### **Do not use Eludril**

- If you are allergic (hypersensitive) to chlorhexidine, chlorobutanol, or any of the other ingredients of Eludril.
- For children under 6 years of age.
- At the same time as toothpastes.

### **Take special care with Eludril**

This medicine is for oral use only. Do not swallow. Avoid contact with the eyes and ears. One of the active ingredients of Eludril (chlorhexidine) is incompatible with some toothpastes, therefore the mouthwash should only be used a short time after usual toothbrushing and thorough rinsing of the mouth. Alternatively, use the mouthwash at a different time of day to when you brush your teeth.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### **Pregnancy and breast-feeding**

You may use Eludril mouthwash if you are pregnant or breast-feeding but as with all medicines at this time, you should discuss it with your doctor or pharmacist first.

### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed with Eludril.

### **Important information about some of the ingredients of Eludril**

This medicine contains:

- sorbitol (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicinal product.
- methyl and propyl parahydroxybenzoates (E218, E216) that can sometimes cause allergic reactions, which may possibly be delayed.
- alcohol. As this medicine is not swallowed there should be no side effect. However, if accidentally swallowed by a child seek immediate medical help.

## **3. How to use Eludril**

Always use Eludril exactly as your doctor has told you. Do not exceed the stated dose. You should check with your doctor or pharmacist if you are not sure.

**As a mouthwash:** Dilute 10 to 15ml in a measuring cup provided for this purpose and fill with lukewarm water to the upper line. Rinse the mouth or gargle two or three times a day.

**As a disinfectant** for removable dentures, prepare in a 1 in 3 dilution of Eludril mouthwash with water. The dentures previously cleansed should be soaked in the solution for one hour.

Eludril is not suitable for children under the age of 6 years.

Always use the measure provided.

### **Do not swallow the mouthwash.**

If there is evidence of irritation or aggravation of your symptoms, a doctor or dentist should be consulted.

### **If you use more Eludril than you should**

If you or a child accidentally swallows or takes too much medicine:

- a small amount should have no side effect
- a large amount (for example a whole bottle) you should immediately contact your doctor or go to the nearest hospital emergency department. If this happens side effects are unlikely but you might have symptoms of digestive discomfort, burning sensation in your mouth and throat, or slight incoordination of your movements.

Always take the labelled medicine package with you, whether there is any medicine left or not.

### **If you forget to use Eludril**

If you forget to use a dose, take it as soon as you remember unless it is time for your next dose. **Do not take a double dose to make up for a missed dose.**

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, Eludril can cause side effects, although not everybody gets them.

The side-effects seen with Eludril are generally mild and disappear after stopping treatment.

If you get a **rash, swelling of the mouth or face, have difficulty in breathing stop using Eludril and seek immediate medical help.** These effects may be symptoms of a severe allergic reaction which is very rare.

If you get swelling or soreness of the inside of the cheeks and irritation of the mouth. **Stop using Eludril** and tell your doctor, dentist or pharmacist. These effects should disappear after stopping treatment.

### **Other side effects:**

- **Peeling of the skin inside the mouth.** If this happens you should dilute 10 ml of the mouthwash in the measuring cup provided for this purpose and fill with lukewarm water to the upper line and also seek medical advice.

- **Change in taste or burning sensation** when you first use Eludril. This usually goes away with continued use.
- **Temporary staining of the tongue.** This disappears after stopping treatment.
- **Temporary staining of the teeth and dentures.** You can help avoid staining by
  - not drinking tea, coffee and red wine, especially one hour after using Eludril,
  - by brushing your teeth, rinsing thoroughly with water and leaving a short time before using Eludril.
  - Where normal brushing is not possible, or if any staining remains, your teeth may need scaling and polishing by your dentist after you have stopped treatment.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, dentist or pharmacist.

## **5. How to store Eludril**

Keep out of the reach and sight of children.

Do not use Eludril after the expiry date which is stamped on the bottle and the label of the bottle. The expiry date refers to the last day of that month.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. Further information**

### **What Eludril contains**

The active substances are chlorhexidine digluconate (0.1 %) and chlorobutanol (0.5 %).

The other ingredients are poloxamer, alcohol, sorbitol solution 70% (crystallising) menthol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), peppermint spirit, purified water.

### **What Eludril looks like and contents of the pack**

Eludril is a clear colourless solution and is available in bottles containing 90, 250 and 500ml. Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

**Pierre Fabre Limited**

Hyde Abbey House  
23 Hyde Street  
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United Kingdom

**Manufacturer**

Pierre Fabre Medicament Production  
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Boulogne  
France

**Other formats:**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

<b>Product Name</b>	<b>Reference Number</b>
<b>Eludril mouthwash:</b>	PL 00603/0012R

This is a service provided by the Royal National Institute of the Blind.

This leaflet was last approved in 01/2011