

## **Package leaflet: Information for the user**

### **Decatylen, 0.25 mg/0.03 mg lozenges** dequalinium chloride/cinchocaine hydrochloride

#### **Read all of this leaflet carefully before you start using this medicine because it contains important information for you**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### **What is in this leaflet**

1. What Decatylen is and what it is used for
2. What you need to know before you use Decatylen
3. How to use Decatylen
4. Possible side effects
5. How to store Decatylen
6. Contents of the pack and other information

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

Decatylen lozenges eliminate bacteria and viruses that can cause throat pain and mouth inflammation. The lozenges also contain an analgesic agent.

Decatylen lozenges are generally well-tolerated and do not cause mucous membrane irritation. Decatylen does not cause dental caries and it can be used by diabetic patients.

Decatylen is used for the antiseptic treatment of the mouth and pharynx, as well as for relieving pain caused by bacterial and fungal infections.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### **2. What you need to know before you use Decatylen**

##### **Do not use Decatylen**

- if you are allergic to dequalinium chloride, cinchocaine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to certain substances known as quaternary ammonium compounds (e.g. benzalkonium chloride).

Do not use Decatylen if you have any of the allergies listed above.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using Decatylen.

Talk to your doctor

- if you have a high fever,
- if your symptoms are not alleviated in one week.

##### **Other medicines and Decatylen**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Toothpaste: the anionic tensides found in regular toothpaste reduce the efficiency of Decatylen. As a result, you should wait for at least half an hour after brushing your teeth before you use Decatylen.

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Dequalinium/cinchocaine can be used during pregnancy and breast-feeding.

### **Driving and using machines**

Even though no corresponding studies have been conducted, it is extremely unlikely that Decatylen affects the ability to drive or use machines.

### **Decatylen contains sorbitol**

This medicinal product contains 1.07 g of sorbitol per lozenge.

Sorbitol is a source of fructose. If you have been told by your doctor that you (or your child) have an intolerance to some sugars, or if you (or your child) have been diagnosed with rare hereditary problems of fructose intolerance (which prevents the body from breaking down fructose), you should consult your doctor before taking this medicine.

Sorbitol may cause gastrointestinal upset and mild diarrhoea.

Sorbitol does not cause tooth decay.

The lozenges are also suitable for use by diabetics.

## **3. How to use Decatylen**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Unless prescribed otherwise by your doctor, the regular dose is:

### Adults and adolescents over 12 years of age:

Allow one lozenge to dissolve in your mouth every 2 hours. After the symptoms of inflammation recede, take 1 lozenge every 4 hours.

### Children over 4 years of age:

Allow one lozenge to dissolve in your mouth every 3 hours. After the symptoms of inflammation recede, take 1 lozenge every 4 hours.

You must talk to a doctor if your symptoms worsen and do not improve after 7 days.

If you feel that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

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

Dequalinium/cinchocaine is generally well-tolerated. Nevertheless, overdosing can cause dizziness, vomiting, and symptoms of oesophageal irritation.

Treatment of an overdose is symptomatic. Alleviating measures can be used if necessary; vomiting and gastric lavage should be avoided.

### **If you forget to use Decatylen**

Do not take a double dose to make up for a forgotten dose.

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

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Allergic reactions accompanied by rash and pruritus have occurred in very rare cases. If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist.

The incidence of side effects is defined as follows: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1,000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1,000$ ), very rare ( $< 1/10,000$ ), unknown (cannot be estimated from available data).

##### *Immune system disorders*

Rare: hypersensitivity reactions

##### *Respiratory, chest, and mediastinal disorders*

Unknown: dyspnoea

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Decatylen

Keep this medicine out of the sight and reach of children.

Do not store at a temperature higher than 25 °C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Decatylen contains

- The active substances are dequalinium chloride and cinchocaine hydrochloride. Each lozenge contains 0.25 mg of dequalinium chloride (*Dequalini chloridi*) and 0.03 mg of cinchocaine hydrochloride (*Cinchocaini hydrochloridi*).
- The other ingredients are sorbitol (E420), talc, magnesium stearate, colloidal silica, peppermint aroma, peppermint oil.

##### What Decatylen looks like and contents of the pack

White round lozenges with a flat edge and a score line on one side and the marking “D” on the other side.

The tablets are packaged in a PVC/Aclar/PVC -aluminium blister package.

The pack contains 20, 30 or 40 lozenges.

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