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Decatylen™ lozenges

Composition

Each lozenge contains:

Active ingredients:

Dequalinium chloride	0.25 mg
Cinchocaine hydrochloride	0.03 mg

Excipients:

Aromatics, sorbitol and other excipients.

Galenical form and amount of active substance per unit

1 lozenge contains: 0.25 mg dequalinium chloride, 0.03 mg cinchocaine hydrochloride.

Indications/Possibilities for use

Decatylen fights the bacteria and fungi which can cause sore throats and infections of the mouth. The lozenges contain a substance called cinchocaine which relieves the painful symptoms.

The lozenges are generally well tolerated and do not cause irritation of the mucous membranes. Decatylen does not cause caries and can also be used by diabetics.

Decatylen is used for the local treatment of acute inflammatory diseases in the mouth and in the throat, for example sore throats, aphthous ulcers, infections of the mouth, hoarseness and catarrh. Your doctor or pharmacist may also recommend Decatylen for use following tonsil operations and tooth extractions in order to promote healing, and also for supportive treatment of angina.

Decatylen is also recommended for treating bad breath.

Posology/Method of administration

Unless otherwise prescribed:

Adults and children above the age of 12 years

Allow 1 lozenge to dissolve slowly in the mouth every 2 hours. After the inflammatory symptoms have subsided, take 1 lozenge every 4 hours.

Children above the age of 4 years

Allow 1 lozenge to dissolve slowly in the mouth every 3 hours. After the inflammatory symptoms have subsided, take 1 lozenge every 4 hours.

Adhere to the dosage described in this package leaflet or prescribed by your doctor. If you have the impression that this medicine is too weak or too strong, please talk to your doctor or pharmacist.

Contraindications

When taking Decatylen, the following side effects can occur: Hypersensitivity reactions may occur in a small number of cases.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Special warnings and precautions for use

If used as directed, no special precautions are required.

Interaction with other medicinal products and other forms of interaction

If used correctly, no special precautions are needed.

If you have a high fever or if there is no improvement within a week, please consult your

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doctor.

Tell your doctor or pharmacist if you

- suffer from any other diseases,
- have any allergies,
- you are taking other medicines (including those you bought yourself!).

Pregnancy/Lactation

May Decatylen be taken during pregnancy or when breast-feeding?

If you are pregnant or seeking to become pregnant, or if you are breast-feeding your child, you should not use Decatylen unless your doctor considers it clearly necessary.

Effects on ability to drive and use machines

The effect of Decatylen™ lozenges on the ability to drive or use machines has not been specifically investigated. However, a negative effect of the medicinal product in this respect is rather unlikely.

Undesirable effects

Patients who are hypersensitive to Decatylen must not use this medicine.

Overdose

There are no data available

Properties/Effects

ATC code: R02A A 02

Mechanism of action

The bactericidal and fungicidal active substance dequalinium chloride has an effect on numerous Gram-positive and Gram-negative bacteria, fungi and spirochaetes and on the pathogens of mixed infections in the mouth and throat. With mild local anaesthesia, the cinchocaine hydrochloride contained in the lozenges alleviates the painful symptoms associated with infections of the mouth and throat.

Development of microorganism resistance to dequalinium chloride is not known.

Since Dequalinium/Cinchocain-Acino is sugar-free, it is also suitable for diabetics. Tooth decay is not encouraged.

The main active substance is barely absorbed.

Pharmacokinetic

There is no data on pharmacokinetics.

Preclinical safety data

There is no relevant data on preclinical safety.

Further remarks

Shelf life

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

Storage conditions

Keep out of the reach and sight of children.

Climatic zone I & II: Do not store above 25°C.

Climatic zone III & IV: Do not store above 30°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.

Presentation

Packs of 10, 20 and 30 lozenges; hospital packs. Not all pack sizes may be marketed

Marketing authorisation holder

Acino Pharma AG, Liesberg.

Date of information

November 2003.