Decatylen™ lozenges

PACKAGE LEAFLET: INFORMATION FOR THE USER

Page: No of pages: 3 11.2003 Ref.:

Patient information

Read all of this leaflet carefully, because it contains important information for you. This medicine has either been prescribed for you personally by your doctor or you have obtained it from your pharmacy without prescription. To get the best results from it, use this medicine according to the leaflet and the instructions of your doctor or pharmacist. Keep this leaflet. You may need to read it again.

Decatylen™ lozenges

What is Decatylen and when is it used?

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.

When must Decatylen not be used?

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

When is caution needed while using Decatylen?

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 doctor.

Tell your doctor or pharmacist if you

suffer from any other diseases,

Up-dated by: Approved by: Sandro Parisi. PhD Annette Mutschler, MSc Regulatory Affairs Generics Pharma Regulatory Affairs Generics Pharma Date: 25 October 2011 Date: 25 October 2011 Version: Decat LOZ PIL e 06

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+ CC 2010-116 (change of dibucaine hydrochloride to cinchocaine hydrochloride)

replaces: Decat_LOZ_PI_e_05

Decatylen[™] lozenges

PACKAGE LEAFLET: INFORMATION FOR THE USER

 Page:
 2

 No of pages:
 3

 Ref.:
 11.2003

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

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 you doctor consider it clearly necessary.

How is Decatylen used?

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.

What are the possible side effects of Decatylen?

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.

What else should be observed?

Decatylen lozenges are sweetened with sorbitol and are therefore also suitable for diabetics.

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.

The information in this leaflet is limited. Further information can be obtained from your doctor or pharmacist.

Composition

Each lozenge contains:

Active ingredients:

Dequalinium chloride 0.25 mg Cinchocaine hydrochlride 0.03 mg

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PACKAGE LEAFLET: INFORMATION FOR THE USER

 Page:
 3

 No of pages:
 3

 Ref.:
 11.2003

Excipients:

Aromatics, sorbitol and other excipients.

Presentation

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

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