Package leaflet: Information for the patient Decalyn lozenges

Dequalinium chloride, lidocaine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, consult your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.
- It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1. What Decalyn is and what it is used for.
- 2. What you need to know before you take Decalyn.
- 3. How to take Decalyn.
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- 5. How to store Decalyn.
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1. What Decalyn is and what it is used for

Decalyn contains dequalinium chloride and lidocaine hydrochloride. Dequalinium chloride is an antiseptic active against a wide range of bacteria, yeasts, fungi (Candida) and viruses.

It kills the micro-organisms associated with various mild infections of the mouth and throat. Lidocaine is a local anesthetic which soothes sore throat and pain on swallowing caused by inflammation.

Decalyn is indicated for infections of the oropharyngeal cavity (local disinfectant and analgesic activity), especially pharyngitis, laryngitis, sore throat in case of cold, thrush (Candida infection), inflammation of the gums and aphtous stomatitis. It is also used as an adjuvant in case of tonsillitis.

What you need to know before you take Decalyn Do not take Decalyn:

- If you are allergic (hypersensitive) to any of the ingredients (listed in section 6) or to local anesthetics.
- If you are under 12 years old.

If any of the above apply to you, do not take Decalyn and consult your doctor or pharmacist.

Warnings and precautions

- Take special care with Decalyn:
- if your symptoms persist
- if you are concerned or think that you are reacting badly to this medicine
- if you have the rare condition Myasthenia Gravis.

If any of these apply to you, consult your doctor or pharmacist.

Other medicines and Decalyn

Consult your doctor or pharmacist if you are taking any of the following:

- Sulphonamides (a class of antibiotics)
- Anticholinesterases (e.g. used to treat Alzheimer's disease)

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

Pregnancy and breast-feeding

The safety of this medicine during pregnancy and breast feeding has not been established. It is not recommended for use during pregnancy and breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist for advice before taking this medicine.

Decalyn contains Sorbitol

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Decalyn contains Potassium

To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How to take Decalyn

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 lozenge to be sucked slowly every 2-3 hours. Do not take any more than 8 lozenges in any 24 hour period.

If you take more Decalyn than you should

If you have accidentally taken too many Decalyn lozenges, consult your doctor or go to hospital straight away. Take the medicine pack and this leaflet with you. If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

4. Possible side effects

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

The following rare side effects may happen with this medicine:

- Allergic reactions and soreness of the tongue. If you experience an allergic reation, stop taking this medicine and consult your doctor or pharmacist.

- Irritation of the oral mucosa.

If you get any side effects, consult your doctor or pharmacist.

This includes any possible side effects not listed in this leaflet.

5. How to store Decalyn

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Decalyn contains

The active substances in Decalyn are dequalinium chloride and lidocaine hydrochloride.

Each lozenge contains dequalinium chloride 0.25 mg and lidocaine hydrochloride 1 mg.

Other ingredients: Sorbitol, acesulfame potassium, magnesium stearate, mint flavour, mannitol, and brilliant blue FCF (E 133). Decalyn lozenges are sugar free.

What Decalyn looks like and contents of the pack

Decalyn lozenges are white round lozenges with blue dots. Availability: Box of 20 lozenges.

Marketing Authorisation Holder and Manufacturer

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