Patient Information Leaflet

SCHEDULING STATUS

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ANDOLEX ANTI-INFLAMMATORY LOZENGES, benzydamine hydrochloride 3,00 mg per lozenge.

Contains sugar: isomalt 2,59 g per lozenge.

Contains sweetener: saccharin sodium 0,65 mg per lozenge.

Read all of this leaflet carefully because it contains important information for you.

ANDOLEX ANTI-INFLAMMATORY LOZENGES is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ANDOLEX ANTI-INFLAMMATORY LOZENGES carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ANDOLEX ANTI-INFLAMMATORY LOZENGES with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What ANDOLEX ANTI-INFLAMMATORY LOZENGES is and what it is used for
2. What you need to know before you take ANDOLEX ANTI-INFLAMMATORY LOZENGES
3. How to take ANDOLEX ANTI-INFLAMMATORY LOZENGES
4. Possible side effects
5. How to store ANDOLEX ANTI-INFLAMMATORY LOZENGES
6. Contents of the pack and other information

1. What Andolex-C Lozenges is and what it is used for

ANDOLEX ANTI-INFLAMMATORY LOZENGES is used for the symptomatic relief of painful conditions of the mouth and throat.

2. What you need to know before you take Andolex-C Lozenges

Do not take ANDOLEX ANTI-INFLAMMATORY LOZENGES:

- if you are hypersensitive (allergic) to benzydamine hydrochloride or any of the ingredients of ANDOLEX ANTI-INFLAMMATORY LOZENGES (listed in section 6).

Warnings and precautions

Take special care with ANDOLEX ANTI-INFLAMMATORY LOZENGES:

- if your sore throat is caused or complicated by a bacterial infection, appropriate antibacterial therapy should be considered;
- if you are allergic to salicylic acid or to other anti-inflammatory painkillers;
- if you have a history of asthma because it can bring on an attack.

Do not give to children under 6 years old.

Other medicines and ANDOLEX ANTI-INFLAMMATORY LOZENGES

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

The safety of using this medicine during pregnancy and while breastfeeding has not been determined.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

ANDOLEX ANTI-INFLAMMATORY LOZENGES should not affect your ability to drive or use machines.

It is not always possible to predict to what extent ANDOLEX ANTI-INFLAMMATORY LOZENGES may interfere with the daily activities of a patient. Patients should ensure that they

do not engage in the above activities until they are aware of the measure to which ANDOLEX ANTI-INFLAMMATORY LOZENGES affects them.

Important information about some of the ingredients in ANDOLEX ANTI-INFLAMMATORY LOZENGES

ANDOLEX ANTI-INFLAMMATORY LOZENGES contains isomalt and may have a laxative effect.

3. How to take ANDOLEX ANTI-INFLAMMATORY LOZENGES

Do not share medicines prescribed for you with any other person.

Always take ANDOLEX ANTI-INFLAMMATORY LOZENGES exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor of pharmacist if you are not sure.

The usual dose for adults and children older than six (6) years, is as follows:

- One lozenge should be sucked slowly every one to two hours as required up to a maximum of 12 lozenges per day.
- Do not chew or swallowed ANDOLEX ANTI-INFLAMMATORY LOZENGES whole. It should be slowly dissolved in the mouth.

If you do not feel better after 7 days, please see your doctor or healthcare professional.

If you take more ANDOLEX ANTI-INFLAMMATORY LOZENGES than you should

- You might experience adverse central nervous system effects such as confusion, anxiety or depression.
- You might suffer from nausea and vomiting.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you take more ANDOLEX ANTI-INFLAMMATORY LOZENGES than you should:

- You might experience adverse central nervous system effects.
- You might suffer from nausea and vomiting.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ANDOLEX ANTI-INFLAMMATORY LOZENGES

Do not take a double dose to make up for forgotten individual doses. Continue with the next dose as normal.

4. Possible side effects

ANDOLEX ANTI-INFLAMMATORY LOZENGES an have side effects.

Not all side effects reported for ANDOLEX ANTI-INFLAMMATORY LOZENGES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ANDOLEX ANTI-INFLAMMATORY LOZENGES, please contact your health care provider for advice.

If the following happens, stop taking ANDOLEX ANTI-INFLAMMATORY LOZENGES and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling in the mouth/ throat which may cause difficulty swallowing or breathing;
- rash or itching especially if affecting the whole body.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to ANDOLEX ANTI-INFLAMMATORY LOZENGES. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

<u>Frequent:</u>

- burning or stinging
- oral numbness

<u>Less frequent:</u>

- dryness of the mouth or thirst,
- tingling, warm feeling in mouth
- altered sense of taste
- sensitivity to light
- swelling of the skin.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ANDOLEX ANTI-INFLAMMATORY LOZENGES. Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at +27 11 087 0000. Website: www.inovapharma.co.za.

5. How to store ANDOLEX ANTI-INFLAMMATORY LOZENGES

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep blister in carton until required for use.

Do not use after the expiry date stated on the label and/or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Content of the pack and other information

What ANDOLEX ANTI-INFLAMMATORY LOZENGES contains

- The active substance is benzydamine hydrochloride 3,00 mg per lozenge.
- The other ingredients are: Aromatic 52.503T, isomalt type M, patent blue V (E131), Quinoline yellow (E104), saccharin sodium.

What ANDOLEX ANTI-INFLAMMATORY LOZENGES looks like and contents of the pack

Round green anise-mint flavoured lozenge packed in blister strips containing 16 lozenges. With prolonged storage the lozenge may become slightly cloudy and rough.

Holder of Certificate of Registration

iNova Pharmaceuticals (Pty) Ltd

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South Africa

This leaflet was last revised in

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Registration number

31/16/0239.

Access to the corresponding Professional Information

The full Professional Information can be found at www.inovapharma.co.za or can be obtained upon request from iNova Pharmaceuticals.