Patient Information Leaflet

SCHEDULING STATUS

S1

ANDOLEX-C ORAL GEL

Benzydamine Hydrochloride 10,0 mg/g and Cetylpyridinium Chloride 1,0 mg/g gel.

Sugar free.

Contains sweetener: Saccharin sodium 0,01 g/10 g

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

ANDOLEX-C ORAL GEL is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use

ANDOLEX-C ORAL GEL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ANDOLEX-C ORAL GEL with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

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

1. What ANDOLEX-C ORAL GEL is and what it is used for

ANDOLEX-C ORAL GEL is used to give temporary relief from painful and inflamed conditions (redness, swelling) in the mouth, mouth ulcers and open sores caused by dentures.

2. What you need to know before you use ANDOLEX-C ORAL GEL

Do not use ANDOLEX-C ORAL GEL:

- if you are hypersensitive (allergic) to benzydamine hydrochloride or cetylpyridinium chloride, or any of the ingredients of ANDOLEX-C ORAL GEL (listed in section 6).
- If a child is younger than six (6) years.

Warnings and precaution

Take special care with ANDOLEX-C ORAL GEL:

- If you have a sore mouth caused by bacteria. Treatment with antibiotics should be considered.

Other medicines and ANDOLEX-C ORAL GEL

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

ANDOLEX-C ORAL GEL with food and drink:

You should not eat or drink anything for at least fifteen (15) minutes after using ANDOLEX-C ORAL GEL.

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

It is not always possible to predict to what extent ANDOLEX-C ORAL GEL 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-C ORAL GEL affects them.

3. How to use ANDOLEX-C ORAL GEL

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

Always use ANDOLEX-C ORAL GEL 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 usual dose for adults and children older than six (6) years, is as follows:

1. Apply approximately 1 cm of gel with finger.
2. Gently massage into sore area.
3. Do not eat or drink for 15 minutes after use.
4. Apply every 2 to 3 hours up to a maximum of twelve (12) times a day.

If you do not feel better, please see your doctor or dentist.

If you use more ANDOLEX-C ORAL GEL than you should

- 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 forget to use ANDOLEX-C ORAL GEL

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

4. Possible side effects

ANDOLEX-C ORAL GEL can have side effects.

Not all side effects reported for ANDOLEX-C ORAL GEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please contact your doctor, pharmacist or other healthcare professional for advice.

- If the following happens, stop using ANDOLEX-C ORAL GEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

o rash or itching

o skin that is sensitive to sunlight

o difficulty breathing

These are all very serious side effects. If you have them, you may have had a serious reaction to ANDOLEX-C ORAL GEL. You may need urgent medical attention or hospitalization.

Tell your doctor or pharmacist if you notice any of the following:

o oral numbness

o burning or stinging sensation

o dryness or thirst, tingling, a warm feeling in your mouth and altered sense of taste.

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-C ORAL GEL.

Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at +27 11 087 0000. Website: www.inovapharma.co.za.

5. How to store ANDOLEX-C ORAL GEL

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep the container tightly closed.

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. Contents of the pack and other information

What ANDOLEX-C ORAL GEL contains

- The active substances are Benzydamine Hydrochloride 10,0 mg/g and Cetylpyridinium Chloride 1,0 mg/g.
- The other ingredients are glycerol, natrosol 250 HHX Pharm, peppermint oil crystal 2110, polysorbate 20, purified water and saccharin sodium.

What ANDOLEX-C ORAL GEL looks like and contents of the pack

ANDOLEX-C ORAL GEL is a clear, colourless, peppermint flavoured oral gel.

ANDOLEX-C ORAL GEL is available in 10,0 g white aluminium laminated tubes, packed into a carton.

Holder of Certificate of Registration

iNova Pharmaceuticals (Pty) Ltd.

15e Riley Road

Bedfordview

South Africa

This leaflet was last revised in

24 November 2020

Registration number

33/16.4/0285

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION FOR HEALTHCARE PROFESSIONALS

Full professional information can be found at www.inovapharma.co.za or can be obtained upon request from iNova Pharmaceuticals.

BOTSWANA
Scheduling Status: 3
Pharmacological classification: ATC: A01A D02 Stomatological preparations: other agents for local oral treatment
Licence Number: BOT 0200516

NAMIBIA
Scheduling Status: NS1
Registration Number: 06/16.4/0095