Patient Information Leaflet

SCHEDULING STATUS

S1

ANDOLEX, benzydamine hydrochloride 22,5 mg/15mℓ, solution.

Sugar free.

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

ANDOLEX is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use ANDOLEX carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ANDOLEX 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 7 days.

What is in this leaflet

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

1. What ANDOLEX is and what it is used for

ANDOLEX is used for symptomatic relief of painful inflammatory conditions of the mouth and throat including:

Traumatic conditions: Inflammation of the pharynx (pharyngitis) following removal of tonsils or after the use of nasogastric tube.

Inflammatory conditions: Pharyngitis, mouth ulcers and oral ulceration due to radiation therapy

Dentistry: For use after dental operations

2. What you need to know before you use ANDOLEX

Do not use ANDOLEX:

- if you are hypersensitive (allergic) to benzydamine hydrochloride or any of the other ingredients of ANDOLEX
- if you are under 12 years old
- if you are pregnant.

Other medicines and ANDOLEX

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

Pregnancy and Breastfeeding

Safety in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before using ANDOLEX.

Driving and using machinery

ANDOLEX has no or negligible influence on the ability to drive and use machines.

ANDOLEX contains alcohol and methyl hydroxybenzoate

ANDOLEX contains alcohol.

ANDOLEX contains the preservative, methyl hydroxybenzoate, which may cause allergic reactions which can be delayed.

3. How to use ANDOLEX

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

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

Oral Rinse

Rinse or gargle with 15 mℓ (approximately one tablespoonful) every 1½ to 3 hours as required for pain relief. ANDOLEX should be expelled from the mouth after use.

Spray

5 to 10 sprays directly onto the painful or inflamed area and swallow gently. Repeat every 1½ to 3 hours as necessary.

Elderly: No special usage recommendation are made for elderly patients.

If you feel that the effect of ANDOLEX is too strong or too weak, talk to your doctor or pharmacist.

If you take more ANDOLEX than you should

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

If you forget to use a dose of ANDOLEX

Do not use a double dose to make up for forgotten individual doses. Use the next dose as previously instructed.

4. Possible side effects

ANDOLEX can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult with your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking ANDOLEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- if you experience difficulty breathing, chest pain or chest tightness, feeling dizzy/faint, severe itching of the skin or raised lumps on the skin, swelling of the face, lips, tongue and throat
- if you experience difficulty to speak or breathe (Laryngospasm)
- if you experience light sensitivity (photodermatitis)
- if you get a rash or hives (urticaria).

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

Tell your doctor as soon as possible if you notice any of the following:

- nausea and vomiting
- light-headedness
- oral tissue numbness
- stinging or burning sensation

- disturbance 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 or nurse. 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.

5. How to store ANDOLEX

Store all medicines out of reach of children

- Store at or below 25 °C
- Do not use after the expiry date stated on the label
- Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What ANDOLEX contains

The active substance is benzydamine hydrochloride 22,5 mg/15 mℓ.

The preservative is methyl hydroxybenzoate 0,1 % m/v.

ANDOLEX contains alcohol 10 % v/v.

The other ingredients are glycerol, saccharin sodium, mouthwash flavour, polysorbate, quinoline yellow, patent blue and purified water.

What ANDOLEX looks like and contents of the pack

A pleasant tasting, clear, green solution.

Oral Rinse: Bottles containing 200 mℓ and 2,5 ℓ

Spray: Bottles containing 30 mℓ

Holder of Certificate of Registration

iNova Pharmaceuticals (Pty) Ltd

15e Riley Road

Bedfordview

South Africa

This leaflet was last revised in

Date of registration: May 1994

Date of latest revision: 15 January 2021.

Registration number

Z/16/40

Final Product Manufacturer

Pharma-Q (Pty) Ltd

50 Commando Road, Industria, Johannesburg

Country of Origin

South Africa

Access to the corresponding Professional Information

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

BOTSWANA	
Scheduling status (**Oral Rinse**):	4
License number:	BOT 9700124

BOTSWANA	
Scheduling status (**Spray**):	3
License number:	BOT 1402675

NAMIBIA	
Scheduling status :	NS1
Registration number :	04/16/0951

ZIMBABWE	
Distribution category:	Pharmacist Initiated Medicine (PIM)
Registration number:	20.3.6 Ear, nose, throat and mouth preparations: Others
Registration number:	98/20.3.6/3302

ZAMBIA: General Sale	
Marketing Authorization No:	Andolex Spray: 478/001L
Andolex Oral Rinse 200 ml:	478/003L

081291

A5524