Patient Information Leaflet

SCHEDULING STATUS

S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ANDOLEX ANALGESIC SPRAY

Benzydamine hydrochloride 0,3 % w/v spray.

Contains sugar: glycerol 0,75 g/15 ml.

Contains sweetener, saccharin sodium 0,01 g/15 ml.

Andolex Analgesic Spray is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Andolex Analgesic Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Andolex Analgesic Spray 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 3 days.

What is in this leaflet

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

1. What Andolex Analgesic Spray is and what it is used for

Andolex Analgesic Spray contains the active substance benzydamine hydrochloride and belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDS. Andolex Analgesic Spray works locally by stopping pain and swelling (inflammation). It is for the treatment of inflammatory and painful conditions of the mouth and throat including conditions such as gingivitis, pharyngitis and laryngitis. Andolex Analgesic Spray can be used after dental procedures and extractions.

2. What you need to know before your use Andolex Analgesic Spray

Do not use Andolex Analgesic Spray:

- if you are hypersensitive (allergic) to benzydamine hydrochloride or any of the other ingredients of Andolex Analgesic Spray (listed in section 6).

Warnings and precautions

Take special care with Andolex Analgesic Spray:

- if you are allergic to salicylic acid or other anti-inflammatory products called NSAIDs, you may also be allergic to Andolex Analgesic Spray,
- if you have asthma, you may have trouble breathing (bronchospasm),
- if you use Andolex Analgesic Spray for a long time, you can become sensitised to it,
- if symptoms persist for more than 3 days, consult your healthcare professional or dentist for advice.

Other medicines and Andolex Analgesic Spray

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

There are no known interactions.

Pregnancy, breastfeeding and fertility

ANDOLEX ANALGESIC SPRAY should not be used during pregnancy and lactation.

Safety in pregnancy and lactation has not been established.

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.

Driving and using machines

Andolex Analgesic Spray has no influence on the ability to drive and use machines.

Andolex Analgesic Spray contains alcohol.

Andolex Analgesic Spray contains the preservative methyl parahydroxybenzoate that may cause allergic reactions which can be delayed.

3. How to use Andolex Analgesic Spray

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

Always use Andolex Analgesic Spray 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 is as follows:

Adults:

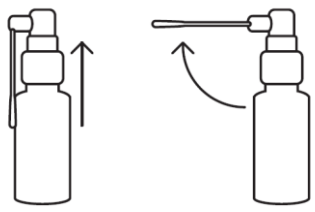
Spray 2 to 4 sprays directly onto the sore/inflamed area and swallow gently. Repeat 2 to 6 times a day as necessary.

Do not exceed the recommended dosage.

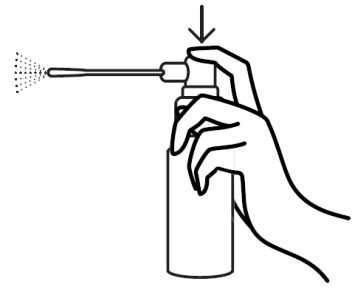
Uninterrupted treatment should not exceed 3 days, except under medical supervision.

How to use the spray

1. To use the spray, hold the bottle in an upright position.
2. Lift the spray-tube through 90° until it is horizontal.



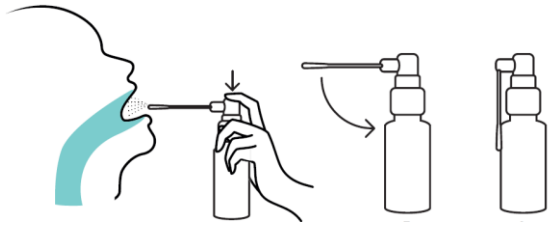
3. The first time you use the spray you need to prime it. Point the spray-tube away from your face. Press down firmly on the plunger until a fine spray appears from the end of the spray-tube. The spray is now ready to use.



4. Aim the spray-tube at the sore part of your mouth or throat and press down on the green plunger again. One press releases one puff.

5. After spraying the desired number of puffs, wipe the end of the spray-tube with a tissue. This helps to stop it becoming blocked.

6. Push the spray-tube back down. This stops any puffs being accidentally released.



If you use more Andolex Analgesic Spray than you should:

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

Symptoms associated with overdose of ingested benzydamine are mainly gastrointestinal symptoms and symptoms of the central nervous system. Most frequent gastrointestinal symptoms are nausea, vomiting, abdominal pain and esophageal irritation. Symptoms of the central nervous system include dizziness, hallucinations, agitation, anxiety and irritability.

The treatment is symptomatic and supportive.

If you forget to use Andolex Analgesic Spray:

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

4. Possible side effects

Andolex Analgesic Spray 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 your health care provider for advice.

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

- hypersensitivity to ANDOLEX ANALGESIC SPRAY including anaphylactic shock or anaphylactic reactions
- a reddish, itchy rash
- loss of consciousness (fainting)
- swelling of the mouth, lips, tongue or throat, which may cause difficulty in swallowing or breathing.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- if you have difficulty breathing, chest pain or discomfort, shortness of breath (cardio-respiratory arrest)
- bluish discolouration of the skin due to reduced oxygen in the blood (cyanosis)
- irregular heart beat (palpitations)

- difficulty breathing (respiratory distress)
- tight chest (asthma)
- choking sensation
- reduced oxygen in the body (asphyxia)
- complications during pregnancy including abortion, premature closing of the blood vessels connecting the arteries (ductus arteriosus) and foetal exposure
- brain death

These are all very serious side effects. You may need urgent medical attention.

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

- dry mouth
- burning, numbness or stinging sensation of the mouth.

The following side effects have been reported spontaneously. Tell your doctor as soon as possible if you notice the following:

- nausea
- anxiety, feeling stressed, restlessness and fear
- dizziness
- eye swelling
- hearing impairment
- upper abdominal pain
- increased secretion of saliva
- abnormal feeling of the mouth
- discomfort swallowing
- reduced sense of feeling of the mouth
- sensitivity to light
- muscular weakness

- difficulty walking
- foreign body sensation
- chest discomfort
- decreased blood pressure

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 Analgesic Spray.

Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at +27 11 087 0000.

5. How to store Andolex Analgesic Spray

Keep all medicines out of the reach and sight of children.

Store at or below 30 °C.

Protect from light.

Do not use after the expiry date stated.

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

The active ingredient is benzydamine hydrochloride (45 mg/15 mℓ). The preservative is methyl parahydroxybenzoate 0,1 % m/v. The other ingredients are alcohol 8 % v/v, castor oil, mint flavour, purified water and saccharin sodium.

Contains sugar: glycerol 0,75 g/15 ml.

Contains sweetener, saccharin sodium 0,01 g/15 ml.

What Andolex Analgesic Spray looks like and contents of the pack

A clear, colourless liquid with a typical mint flavour in a plastic metered dose spray container containing 15 ml in a printed carton box.

Holder of the Certificate of Registration

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2007

Telephone number: +27 11 087 0000

This leaflet was last revised on

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51/16.5/0924

Access to the corresponding Professional Information for Healthcare Professionals

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