PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

ANDOLEX-C Oral Rinse, 22,5 milligram, 18 milligram, solution

Benzydamine hydrochloride, Chlorhexidine gluconate

Contains sugar (sorbitol solution) 3,75 g/15 ml

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ANDOLEX-C Oral Rinse 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-C Oral Rinse is and what it is used for
2. What you need to know before you use ANDOLEX-C Oral Rinse
3. How to use ANDOLEX-C Oral Rinse
4. Possible side effects
5. How to store ANDOLEX-C Oral Rinse
6. Contents of the pack and other information

1. What ANDOLEX-C Oral Rinse is and what it is used for

ANDOLEX-C Oral Rinse is used for the relief of painful inflammatory conditions of the mouth and throat.

ANDOLEX-C Oral Rinse helps to reduce the development of plaque.

2. What you need to know before you use ANDOLEX-C Oral Rinse

Do not take/use ANDOLEX-C Oral Rinse:

- if you are under 6 years old.
- if you are pregnant.
- if you are hypersensitive (allergic) to benzydamine, chlorhexidine or any of the other ingredients of ANDOLEX-C Oral Rinse (listed in section 6).

Warnings and precautions

Take special care with ANDOLEX-C Oral Rinse:

- if stinging or burning occurs.
- ANDOLEX-C Oral Rinse can be diluted with water to avoid contact with the eyes.
- should ANDOLEX-C Oral Rinse come into contact with the eyes, wash out thoroughly with water.
- Sorbitol may have an effect on blood sugar levels in patients with diabetes mellitus. Patients with the rare hereditary condition of sorbitol intolerance should not use this medicine.
- your treatment should not exceed 7 days except under medical supervision.

Children and adolescents

Not for children under 6 years old (see section “do not use ANDOLEX-C Oral Rinse”)

Other medicines and ANDOLEX-C Oral Rinse

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

Some of the toothpastes are not compatible with chlorhexidine. At least 30 minutes should be allowed to elapse between teeth brushing and rinsing with ANDOLEX-C Oral Rinse in order to ensure that the antiplaque effect is not reduced.

Pregnancy and breastfeeding

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 healthcare provider for advice before using ANDOLEX-C Oral Rinse.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machines

ANDOLEX-C Oral Rinse has no or negligible influence on the ability to drive and use machines.

ANDOLEX-C Oral Rinse contains alcohol

ANDOLEX-C Oral Rinse contains 1110 mg of alcohol (ethanol) in each 15 ml dose which is equivalent to less than 30 ml beer or 12 ml wine. This small amount of alcohol in ANDOLEX-C Oral Rinse will not have any noticeable effects.

3. How to use ANDOLEX-C Oral Rinse

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

Always use ANDOLEX-C Oral Rinse exactly as your doctor or pharmacist has told you. Check with you doctor or pharmacist if you are not sure.

Adults

Gargle:

Gargle with 15 ml (approximately one tablespoon) for at least 30 seconds at 1½ to 3 hourly intervals, as needed. The solution should be expelled from the mouth after use.

Rinse for oral lesions:

15 ml (approximately one tablespoon) which should be held in the mouth and swirled around for at least 30 seconds, with repeat use every 1½ to 3 hours throughout the day, as needed. The solution 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.

Children (6 to 12 years)

Use 5 to 15 ml as a gargle if able to do so, or as an oral rinse, every 3 hours.

How to clean and care for your ANDOLEX-C Oral Rinse spray:

Rinse the actuator spindle and nozzle after every use to avoid sporadic blockages of the spray tube. Rinse the spray tube in warm, running water for at least 30 seconds and let the water run through the spray tube. This is very important as sometimes the small opening where the medicine comes out can become blocked. Shake off the excess water and leave the spray tube to dry completely. Blockage from medication build-up is more likely to occur if the spray tube is not allowed to dry thoroughly. The spray should be stored in an upright position.

If you take more ANDOLEX-C Oral Rinse than you should

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

You may feel the following:

Nausea and vomiting.

Abdominal pain

Oesophageal irritation.

Central nervous system effects have been reported following overdose. Symptoms include:

dizziness

hallucinations

agitation

anxiety

irritability.

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-C Oral Rinse

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

4. Possible side effects

ANDOLEX-C Oral Rinse can have side effects.

Not all side effects reported for ANDOLEX-C Oral Rinse are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ANDOLEX-C Oral Rinse, please consult with your healthcare provider for advice.

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

- if you experience difficulty to breathe (bronchospasm)
- if you experience difficulty to speak (laryngospasm)
- if you get hives or a rash, or if itching occurs
- if you are sensitive to light.

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

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

Less frequent side effects:

- oral tissue numbness
- stinging sensation, oral pain
- dryness of the mouth or thirst
- disturbance of taste
- reversible discolouration of the teeth and tongue
- swelling the salivary (parotid) glands
- shedding or scaling of the inside of your mouth (oral desquamation).

Unknown frequency

- painless swelling under the skin
- nausea and vomiting (gastro-intestinal disturbances)
- light-headedness

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 nurse. You can also report side effects to 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 Rinse.

5. How to store ANDOLEX-C Oral Rinse

Store all medicines out of reach of children.

Store at or below 30 °C in the carton

Store in an upright position

Protect from light

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-C Oral Rinse contains

The active substances are benzydamine hydrochloride 22,5 mg/15ml and chlorhexidine gluconate 18 mg/15ml. ANDOLEX-C Oral Rinse contains alcohol 9 % *v/v*.

Other ingredients include sorbitol solution 70 %, polyoxyl 40 hydrogenated castor oil, peppermint oil, aniseed, carmoisine and purified water.

What ANDOLEX-C Oral Rinse looks like and contents of the pack

ANDOLEX-C Oral Rinse is a clear, pinkish red liquid with an odour of peppermint/aniseed.

Oral Rinse:	Bottles containing 200 ml and 2L.
Spray:	Bottles containing 30 ml.

Holder of Certificate of Registration

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