

Applicant:	iNOVA Pharmaceuticals (Pty) Ltd	Patient Information Leaflet
Product Name (Dosage form):	ANDOLEX-CPC mouthwash	
	Contains Each 100 ml contains: active ingredients: 0,15 g benzydamine hydrochloride (equal to 0,134 g benzydamine) and 0,05 g cetylpyridinium chloride (equal to 0,0425 g cetylpyridinium).	
Date registered: 30 August 2022		

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

ANDOLEX-CPC 22,5 mg/15 ml + 7,5 mg/15 ml mouthwash

Benzydamine hydrochloride and cetylpyridinium chloride

Contains polyoxyethylene hydrogenated castor oil 40, ethanol (96 %)

Contains sweetener (saccharin sodium 0,5 mg per 100 ml)

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ANDOLEX-CPC with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5-7 days.

What is in this leaflet

1. What ANDOLEX-CPC is and what it is used for
2. What you need to know before you take ANDOLEX-CPC
3. How to take ANDOLEX-CPC
4. Possible side effects



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5. How to store ANDOLEX-CPC

6. Contents of the pack and other information

1. What ANDOLEX-CPC is and what it is used for

ANDOLEX-CPC contains the active substances benzydamine hydrochloride (a nonsteroidal anti-inflammatory and analgesic) and cetylpyridinium chloride (an antiseptic).

ANDOLEX-CPC is used as an antiseptic, anti-inflammatory and pain reliever in mouth and gum irritations, gingivitis and stomatitis. It is also indicated before and after tooth extractions.

2. What you need to know before you use ANDOLEX-CPC

Do not use ANDOLEX-CPC if:

- you are hypersensitive to benzydamine hydrochloride, cetylpyridinium chloride or to any of the other ingredients of ANDOLEX-CPC (listed in section 6).

Warnings and precautions

Take special care with ANDOLEX-CPC:

- Prolonged use can give rise to sensitisation phenomena (allergic reactions). In this case, stop the treatment and consult your doctor to start a suitable therapy. See section 4 "Possible side effects".



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- For those who carry out sports: the use of ethyl alcohol-containing medicines can determine doping test positivity in relation to the blood alcohol concentration limits indicated by some sports federations.

ANDOLEX-CPC contains a high amount of alcohol which may affect recovering alcoholics. Because of the high alcohol concentration ANDOLEX-CPC may interfere with the alcohol test results in case you are suspected of drunken driving.

Other medicines and ANDOLEX-CPC

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Avoid the simultaneous use of other antiseptics.

Pregnancy, breastfeeding and fertility

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-CPC.

Driving and using machines

It is not always possible to predict to what extent ANDOLEX-CPC may interfere with the daily activities of a patient. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the extent to which ANDOLEX-CPC affects you.



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3. How to take ANDOLEX-CPC

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

Always take ANDOLEX-CPC exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Rinse with 15 ml of mouthwash, 2-3 times a day. ANDOLEX-CPC can be used, if necessary, at any time of the day. Use for a maximum period of 5-7 days. Rinse with 15 ml of mouthwash, 2-3 times a day, using the special measuring cup.

Do not swallow.

If you use more ANDOLEX-CPC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. In case of overdose you may experience a feeling of enthusiasm and eagerness (excitement), uncontrolled muscle spasms (convulsions), sweating, loss of full control of body movements (ataxia), shaking movements (tremors), impaired relationship with reality (psychosis) and vomiting.

If you forget to use ANDOLEX-CPC

Do not use a double dose to make up for forgotten individual doses. Continue with the next dose at the scheduled time.



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4. Possible side effects

ANDOLEX-CPC can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

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

Tell your doctor if you notice any of the following:

Unknown frequency of side effects

- numbness in the mouth
- mild and temporary burning at the application site

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

Reporting of side effects



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If you get side effects, talk to your doctor, 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-CPC.

5. How to store ANDOLEX-CPC

Store all medicine out of sight and reach of children.

Store at or below 25 °C in a dry place. Keep the bottle tightly closed.

Store in the original package until required for use in order to protect the medicine from light and moisture.

Shelf life after the first opening of the glass bottle is 1 year.

Do not use the mouthwash after the expiry date shown on the container.

Return the expired medicine to your pharmacist for safe disposal.

6. Contents of the pack and other information

What ANDOLEX-CPC contains

The active ingredients are benzydamine hydrochloride and cetylpyridinium chloride.

The other ingredients are ethanol 96 %, glycerol, macrogolglycerolhydroxystearate,40, mint flavour, Patent Blue (V 131), purified water, Quinoline Yellow (E 104), saccharin and sodium hydrogen carbonate (pH adjuster).

What ANDOLEX-CPC looks like and contents of the pack



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ANDOLEX-CPC is a clear liquid, green in colour, with typical mint flavour.

Colourless 120 and 240 ml glass bottle, closed with a polypropylene screw cap with a polyethylene inner cap and an attached measuring cup.

The bottle and the plastic beaker are packaged in a cardboard box together with the patient information leaflet.

Holder of Certificate of Registration

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This leaflet was last revised in

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