

MODULE 1.3.2

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

CEPACOL ANTI-INFLAMMATORY MOUTHWASH (Solution)

Benzydamine hydrochloride 22,50 mg/15 ml

Contains sweetener: Saccharin sodium 500

Contains alcohol: Ethanol 96 % (10 % v/v)

Preservative: Methylparaben 0,15 % m/v

Sugar free

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

CEPACOL ANTI-INFLAMMATORY MOUTHWASH is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH 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 CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH is and what it is used for
2. What you need to know before you take CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH

3. How to take CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH
4. Possible side effects
5. How to store CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH
6. Contents of the pack and other information

1. What CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH is and what it is used for

CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH is a solution which contains an active ingredient Benzydamine which exerts a local anti-inflammatory and analgesic action.

CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH is used to relieve painful inflammatory (swollen) conditions of the mouth and throat including:

Minor injury conditions: Pharyngitis (inflammation of the part of the throat behind the soft palate) following the use of nasogastric tube or tonsillectomy (surgical removal of the tonsils).

Inflammatory conditions: aphthous ulcers (small ulcers occurring singly or in groups in the mouth as white or red spots), management of mouth ulcers and mucositis (inflammation of the part of the throat behind the soft palate) due to radiotherapy

After dental operations.

2. What you need to know before you CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH

Do not take CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH if:

- you are hypersensitive (allergic) to Benzydamine hydrochloride or to any of the other ingredients of CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH (listed in section 6).
- you are a child under the age of 12 years
- you are pregnant or breastfeeding your baby

Warnings and precautions

CEPACOL ANTI-INFLAMMATORY MOUTHWASH should not be used uninterruptedly for

longer than 7 days except under medical supervision.

CEPACOL ANTI-INFLAMMATORY MOUTHWASH use is not advisable in patients with hypersensitivity to acetylsalicylic acid or other NSAIDs.

Caution should be exercised in patients suffering from or with a previous history of bronchial asthma.

CEPACOL ANTI-INFLAMMATORY MOUTHWASH should generally be used undiluted, but if stinging occurs, the rinse may be diluted with water.

Do not swallow.

Avoid contact with eyes.

This medicine contains 1,5 ml alcohol (ethanol) in each 15 ml.

Other medicines and CEPACOL ANTI-INFLAMMATORY MOUTHWASH

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

Pregnancy, breastfeeding and fertility

CEPACOL ANTI-INFLAMMATORY MOUTHWASH should not be used during pregnancy and lactation. There is no proof of birth defects in animal studies.

If you are pregnant or breastfeeding your 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 CEPACOL ANTI-INFLAMMATORY MOUTHWASH 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 CEPACOL ANTI-INFLAMMATORY MOUTHWASH affects them.

3. How to take CEPACOL ANTI-INFLAMMATORY MOUTHWASH

DO NOT EXCEED THE RECOMMENDED DOSE.

Rinse or gargle with 15 ml (approximately one tablespoonful) every 1 ½ to 3 hours as required for pain relief. The solution should be expelled from the mouth after use.

Do not swallow.

Contact with the eyes should be avoided

CEPACOL ANTI-INFLAMMATORY MOUTHWASH should generally be used undiluted, but if "stinging" occurs, the rinse may be diluted with water

Elderly: No special usage recommendations are made for elderly

Do not share medicines recommended for you or your child with any other person.

Always take CEPACOL ANTI-INFLAMMATORY MOUTHWASH exactly as described in this leaflet. Check with your doctor if you are not sure.

Do not swallow

If you use more CEPACOL ANTI-INFLAMMATORY MOUTHWASH than you should

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 CEPACOL ANTI-INFLAMMATORY MOUTHWASH

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

4. Possible side effects

CEPACOL ANTI-INFLAMMATORY MOUTHWASH can have side effects

Not all side effects reported for CEPACOL ANTI-INFLAMMATORY MOUTHWASH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CEPACOL ANTI-INFLAMMATORY MOUTHWASH, please consult your health care provider for advice.

If any of the following happens, stop using CEPACOL ANTI-INFLAMMATORY

MOUTHWASH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Tightening of the muscles in the lungs
- Oral numbness;
- burning or stinging sensation,
- nausea,
- vomiting
- an altered sense of taste.
- Hypersensitivity reactions including redness and itchiness of skin and sensitivity to light

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

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

Reporting of side effects

If you get any 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 CEPACOL ANTI-INFLAMMATORY MOUTHWASH

5. How to store CEPACOL ANTI-INFLAMMATORY MOUTHWASH

Store all medicines out of reach of children

Store at or below 25 °C

Keep well closed

Do not take 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 systems (e.g. toilets)

6. Contents of the pack and other information

What CEPACOL ANTI-INFLAMMATORY MOUTHWASH contains

The active substance is Benzydamine hydrochloride 22,50 mg/15 ml

The other ingredients are: Sodium citrate, citric acid monohydrate; glycerol; polysorbate (tween) 80; spectracol quinoline yellow; spectracol brilliant blue, peppermint flavour, purified water

What CEPACOL ANTI-INFLAMMATORY MOUTHWASH looks like and contents of the pack

A clear green solution, free from particulate matter, with a peppermint odour

Packed in:

200 ml Clear, Round Polyethylene Terephthalate (PET) bottle with a white child proof screw-on cap, packed in an outer cardboard box.

200 ml Clear, Round Polyvinyl Chloride (PVC) bottle with a white screw-on PP cap; packed in an outer cardboard box.

200 ml Clear, Round Glass bottle MEDROPP Generic with a white screw on cap, packed in an outer cardboard box.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69,

Bryanston, 2021, RSA

www.adcock.com

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Access to the corresponding Professional Information

The PI will be included in the medicine package.