

## MODULE 1.3.1.1

### APPROVED PROFESSIONAL INFORMATION

#### SCHEDULING STATUS

S1

#### 1. NAME OF THE MEDICINE

**CEPACOL ANTI-INFLAMMATORY MOUTHWASH (Solution)**

**Benzydamine hydrochloride 22,50 mg/15 ml**

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Each 15 ml contains:

Benzydamine hydrochloride 22,50 mg

##### Preservative:

Methylparaben 0,15 % m/v

##### Contains alcohol:

Ethanol 96 % (10 % v/v)

##### Contains sweetener:

saccharin sodium 500 5,40 mg

Sugar free

For full list of excipients, see section 6.1

#### 3. PHARMACEUTICAL FORM

Solution

CEPACOL ANTI-INFLAMMATORY MOUTHWASH:

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

#### 4. CLINICAL PARTICULARS

#### **4.1 Therapeutic indications**

CEPACOL ANTI-INFLAMMATORY MOUTHWASH is used for the symptomatic relief of painful inflammatory conditions of the mouth and throat such as:

Traumatic conditions: Pharyngitis following the use of nasogastric tube or tonsillectomy.

Inflammatory conditions: Pharyngitis, aphthous ulcers and oral ulceration due to radiotherapy.

Dentistry: After dental operations.

#### **4.2 Posology and method of administration:**

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

#### **4.3 Contraindications**

- Hypersensitivity to Benzydamine hydrochloride or to any of the ingredients in CEPACOL ANTI-INFLAMMATORY THROAT MOUTHWASH.
- Children under the age of 12 years
- Pregnancy and Lactation (see Section 4.6)

#### **4.4 Special warnings and precautions for use**

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.

#### **4.5 Interaction with other medicines and other forms of interaction**

Recommended not to use simultaneously with other medicines.

Interaction with other medicines has not been established.

#### **4.6 Fertility, pregnancy and lactation**

CEPACOL ANTI-INFLAMMATORY MOUTHWASH should not be used during pregnancy and lactation.

Fertility: There is no evidence of a teratogenic effect in animal studies.

#### **4.7 Effects on ability to drive and use machines**

Factors that affect the ability to drive and use machines have not been established.

#### **4.8 Undesirable effects**

##### **Respiratory, thoracic and mediastinal disorders:**

Bronchospasm

##### **Gastrointestinal disorders:**

Oral numbness; burning or stinging sensation, nausea, vomiting and an altered sense of taste.

##### **Skin and subcutaneous tissue disorders:**

Hypersensitivity reactions including urticaria and photosensitivity.

##### **Immune system disorder:**

Anaphylactic reaction which can be potentially life threatening and hypersensitivity reactions, angioedema.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

#### **4.9 Overdose**

There is no specific antidote for benzydamine. Treatment should be symptomatic and supportive. (see Section 4.8)

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Class of the medicine: A.16.5 Ear, nose and throat preparations

Benzydamine hydrochloride has local analgesic and anti-inflammatory properties.

Benzydamine hydrochloride exerts this action by stabilising the cell membrane and inhibiting the synthesis of prostaglandins.

#### **5.2 Pharmacokinetic properties**

The systemic absorption of the mouthwash doses of benzydamine hydrochloride is relatively low compared to oral doses and may greatly diminish the potential for any systemic medicine effects.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

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

#### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

24 months

### **6.4 Special precautions for storage**

Keep well closed.

Store at or below 25 °C.

### **6.5 Nature and contents of container**

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

### **6.6 Special precautions for disposal**

No special requirements

## **7. HOLDER OF CERTIFICATE OF REGISTRATION**

Adcock Ingram Limited

1 New Road

Erand Gardens,

Midrand 1685

Private Bag X69,

Bryanston, 2021

[www.adcock.com](http://www.adcock.com)

## **8. REGISTRATION NUMBER (S)**

55/16.5/0135

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

19 February 2021

**10. DATE OF REVISION OF THE TEXT**

Not Applicable