**SCHEDULING STATUS**

S1

## 1 NAME OF THE MEDICINE

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

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains: Benzydamine hydrochloride 22,5 mg

Chlorhexidine gluconate 18 mg

*Excipient with known effect:*

Alcohol 9 % *v/v*

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

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution

A clear, pinkish red liquid with an odour of peppermint/aniseed.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the relief of minor infections and painful inflammatory conditions of the mouth and throat.

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

### 4.2 Posology and method of administration

**Posology**

**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 and not swallowed.

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.

ANDOLEX-C Oral Rinse should generally be used undiluted, but if stinging occurs, the rinse may be diluted with water.

**Paediatric population**

It is recommended that 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**.**

Avoid contact with the eyes.

**How to clean and care for ANDOLEX-C 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.

Note: 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.

**Method of administration**

ANDOLEX-C Oral Rinse, solution should be gargled or rinsed or sprayed in the mouth, after use the solution should be expelled from the mouth and not swallowed.

**4.3 Contraindications**

Patients with known hypersensitivity to benzydamine, chlorhexidine or to any of the other ingredients of the formulation (see section 6.1).

ANDOLEX-C Oral Rinse is not recommended in children under 6 years of age.

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

Benzydamine use is not advisable in patients with hypersensitivity to acetylsalicylic acid or other NSAIDs.

Do not swallow. If a burning or stinging sensation occurs, ANDOLEX-C Oral Rinse can be diluted with water.

Avoid contact with the eyes. Should it come in contact with the eyes, wash out thoroughly with water.

Uninterrupted treatment should not exceed 7 days except under medical supervision.

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.

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

**Paediatric population**

Not recommended for children under 6 years of age (see section 4.3).

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

Anionic agents in some toothpastes are incompatible with chlorhexidine. In order that the antiplaque effect of chlorhexidine is not reduced, it has been recommended that at least 30 minutes should be allowed to elapse between teeth brushing and rinsing with ANDOLEX-C Oral Rinse.

**4.6 Fertility, pregnancy and lactation**

**The safety of ANDOLEX-C Oral Rinse in pregnancy and lactation has not been established.**

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

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

**4.8 Undesirable effects**

| **MedDRA System Organ Class** | **Frequency** | **Adverse reaction** |
|---|---|---|
| **Immune system disorders** | Less frequent | Hypersensitivity reactions |
| | Frequency unknown | Anaphylactic reactions (signs of which may include difficulty breathing, chest pain or chest tightness, and/or feeling dizzy/faint, severe itching of the skin or raised lumps on the skin, swelling of the |

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|---|---|---|
| | | face, lips, tongue and/or throat, and which may be potentially life-threatening. |
| **Respiratory, thoracic and mediastinal disorders** | Less frequent | Laryngospasm or bronchospasm |
| **Gastrointestinal disorders** | Less frequent | Oral numbness (hypoesthesia) and a stinging feeling in the mouth (oral pain) |
| | Frequency unknown | Gastro-intestinal disturbances |
| **Skin and subcutaneous tissue disorders** | Less frequent | Pruritus, urticaria, photosensitivity reaction (e.g. photodermatitis), and rash |
| | Frequency unknown | Angioedema |
| **General disorders and administration site conditions** | Less frequent | Dryness or thirst, reversible discolouration of the tongue and teeth, transient disturbance of taste, oral desquamation, swelling of the parotid gland. |

*Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare 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**

See Section 4.8.

Adverse effects have been reported following overdosage**.** Symptoms include nausea, vomiting, sore throat, and abdominal pain.

Adverse central nervous system effects have been reported following overdose. Symptoms of the central nervous system include dizziness, hallucinations, agitation, anxiety and irritability. There is no specific antidote for benzydamine and should excessive quantities be ingested the treatment should be symptomatic and supportive.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

A. 16.4 Nasopharyngeal and bucco-pharyngeal antiseptics

Pharmacotherapeutic group: Other anti-inflammatory and antrheumatic agents, nonsteroids /Anti-inflammatory preparations, non-steroids for topical use, ATC code: M01AX07/M02AA05.

Benzydamine hydrochloride has local analgesic and anti-inflammatory properties by stabilising the cellular membrane and inhibiting prostaglandin synthesis.

Chlorhexidine has antiseptic and disinfectant properties.

**5.2 Pharmacokinetic properties**

**Benzydamine**

When administered as a local application, benzydamine has a low systemic absorption which reduces the potential of systemic side effects. Metabolism is mainly through oxidation, dealkylation and conjugation.

**Chlorhexidine**

Minimal systemic absorption is observed. Chlorhexidine is poorly absorbed from the gastrointestinal tract and skin.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sorbitol solution 70 %

Ethanol 96 %

Polyoxyl 40 hydrogenated castor oil

Peppermint oil

Aniseed liquid flavour

Carmoisine

Purified water

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

24 months

### 6.4 Special precautions for storage

Store in the carton, at or below 30 °C, in an upright position.

Protect from light.

**6.5 Nature and contents of container**

Oral Rinse: Clear plastic bottles containing 200 ml and 2 litres.

Spray: Clear glass of plastic PET bottles containing 30 ml and 50 ml.

**6.6 Special precautions for disposal and other handling**

No special requirements.

## 7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

15e Riley Road

Bedfordview

South Africa

## 8 REGISTRATION NUMBER(S)

31/16.4/0143

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

Date of registration: 02 October 2002

## 10 DATE OF REVISION OF THE TEXT

05 September 2021