Professional Information for CHLORZYD ANTISEPTIC GARGLE

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

CHLORZYD ANTISEPTIC GARGLE (solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains:

Benzydamine hydrochloride 22,5 mg

Chlorhexidine gluconate 18 mg

Contains sugar: Sorbitol (70%): 1,5 g

Contains sweetener: Sucralose: 5,25 mg

Solvent: Propylene glycol: 1,5 g

For the full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Oral rinse.

Clear solution having green colour, sweet-bitter taste, refreshing mint odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

mouth.

CHLORZYD ANTISEPTIC GARGLE helps 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 - 3 hourly intervals, as required. The solution should be expelled from the mouth after use and not swallowed.

Rinse for oral lesions:

Use 15 ml (approximately one tablespoon) should be held in the mouth and swirled around for at least 30 seconds, repeating every at 1½ - 3 hourly intervals throughout the day, as required. The solution should be expelled from the mouth after use.

Children (6 – 12 years of age)

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

Method of administration

Use as oral gargle. Do not swallow.

CHLORZYD ANTISEPTIC GARGLE should generally be used undiluted, but if stinging occurs, the rinse may be diluted with water.

Avoid contact with the eyes.

4.3 Contraindications

CHLORZYD ANTISEPTIC GARGLE is contraindicated in patients with a known hypersensitivity to benzydamine, chlorhexidine or any of the other inactive ingredients in this oral rinse (see Section 6.1).

CHLORZYD ANTISEPTIC GARGLE is not recommended to be used in children under 6 years, as safety and efficacy has not been established.

4.4 Special warnings and precautions for use

Do not swallow. If a burning or stinging sensation occurs,

CHLORZYD ANTISEPTIC GARGLE can be diluted with water. Avoid contact with the eyes. Should it come in contact with the eyes, wash out thoroughly with water.

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

The use of benzydamine, a component of CHLORZYD ANTISEPTIC GARGLE is not advisable in patients with hypersensitivity to aspirin or other NSAIDs.

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

In case of soreness, swelling or irritation of the mouth, use of the product should be discontinued and consult a healthcare professional.

CHLORZYD ANTISEPTIC GARGLE is not compatible with anionic agents which are usually present in conventional dentifrices, including toothpaste. These should therefore be used before CHLORZYD ANTISEPTIC GARGLE (rinsing the mouth between applications) or at a different time of day (se Section 4.5).

If swelling or difficulty breathing occurs, stop using the product and seek immediate medical help. When initiating the use of CHLORZYD ANTISEPTIC GARGLE the following side effects may be experienced: transient disturbances of taste sensation and numbness, tingling or burning sensation of the tongue. These effects usually diminish with continued use. If these persist, consult a healthcare professional.

A non-permanent discolouration of the teeth and tongue may occur. The stain can be prevented by reducing the consumption of dietary chromagens such as tea, coffee or red wine. In the case of dentures this can be prevented by cleaning with a conventional denture cleaner. In certain cases, professional treatment, (scaling and polishing) may be necessary to remove the stain completely. Stained anterior tooth-coloured restorations with poor margins or rough surfaces which are not effectively cleaned by professional prophylaxis may require replacement. Similarly, where normal tooth brushing is not possible, for example with intermaxillary fixation, or with extensive orthodontic appliances, scaling and polishing may also be required once the underlying condition has been resolved.

Excipients:

This medicine contains 1,5 g propylene glycol in each 15 ml.

As CHLORZYD ANTISEPTIC GARGLE should not be swallowed, the quantity of propylene glycol does not necessitate warning.

This medicine contains 1,5 g sorbitol in each 15 ml.

The additive effect of concomitantly administered products containing sorbitol (or fructose)

and dietary intake of sorbitol (or fructose) should be taken into account.

The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicines and other forms of interaction

Chlorhexidine salts are incompatible with soap and other anionic components, included in some toothpastes. To prevent the reduction in antiplaque effect of chlorhexidine, it has been recommended that at least 30 minutes should be allowed to elapse between teeth brushing and rinsing with CHLORZYD ANTISEPTIC GARGLE.

4.6 Fertility, pregnancy and lactation

The safety of CHLORZYD ANTISEPTIC GARGLE in pregnancy and breastfeeding has not been established.

CHLORZYD ANTISEPTIC GARGLE is used as a gargle and is not for oral ingestion.

4.7 Effects on ability to drive and use machines

It is not known if CHLORZYD ANTISEPTIC GARGLE may influence the patient's ability to drive or use machines.

4.8 Undesirable effects

The most frequently reported undesirable effect was numbness and a stinging feeling in the mouth.

System Organ Class	**Frequency**	**Adverse reaction**
Immune system disorders	*Less frequent*	Hypersensitivity reactions including urticaria, rash, bronchospasm or laryngospasm and photodermatitis
	Frequency unknown	Serious allergic reaction (anaphylactic shock), 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 face, lips, tongue and/or throat (angioedema), and which may be potentially life-threatening
Nervous system disorders	*Frequent*	Aguesia / dysguesia, glossodynia, oral paraesthesia/ hypoaesthesia
Respiratory, thoracic and mediastinal disorders	*Less frequent*	Laryngospasm or bronchospasm
Gastrointestinal	*Frequent*	Tongue coated, dry mouth

System Organ Class	Frequency	Adverse reaction
disorders	*Less frequent*	Oral numbness (hypothesia) and a stinging feeling in themouth (oral pain)
	Frequency unknown	Gastro-intestinal disturbances
General disorders and administrative site conditions	*Less frequent*	Oral tissue numbness and stinging sensation, dryness or thirst, reversible discolouration of the tongue and teeth, 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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Medicine Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Adverse effects have been reported following overdosage.

Symptoms include nausea, vomiting, sore throat, and abdominal pain. Central nervous system adverse effects have been reported following overdose, including the following

symptoms: dizziness, hallucinations, agitation, anxiety, and irritability.

There is no specific antidote for benzydamine. Treatment should be symptomatic and supportive should excessive quantities be ingested.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other agents for local oral treatment

ATC code: A01A D02

Pharmacological classification: A 16.4 Nasopharangeal and bucco-pharyngeal antiseptics.

Benzydamine hydrochloride:

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

Chlorhexidine gluconate:

Chlorhexidine has antiseptic and disinfectant properties.

5.2 Pharmacokinetic properties

Benzydamine hydrochloride:

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

Chlorhexidine gluconate:

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate, Ecocool MP (flavour), mint essence, Patent V blue, polysorbate 20, propylene glycol, purified water, quinolone yellow, sodium citrate dihydrate, sorbitol (70 %) and sucralose.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 ºC.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

CHLORZYD ANTISEPTIC GARGLE is packed in an amber PET bottle with a white and blue scaled cap topped with a measuring cup (15 ml). This is packaged in a cardboard box.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets

Woodstock, Cape Town

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8. REGISTRATION NUMBER(S)

53/16.4/0606

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 March 2024

10. DATE OF REVISION OF THE TEXT

Not applicable.