Professional Information

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

CHLORZYD ANTISEPTIC THROAT SPRAY (solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 30 ml contains:

Benzydamine hydrochloride 45,00 mg (0,15 % *w/v*)

Chlorhexidine gluconate 36,00 mg (0,12 % *w/v*)

Contains sugar: Sorbitol (70%): 3000 mg

Contains sweetener: Sucralose: 10,5 mg

Solvent: Propylene glycol: 3000 mg

For the full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Oral spray.

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.

4.2 Posology and method of administration

Posology

Adults and children over 6 years:

5 to 10 sprays directly onto the painful or inflamed area and swallow gently. Repeat every 1½ to 3 hours as necessary.

Paediatric:

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

Method of administration

Use as an oral spray.

Avoid contact with the eyes.

4.3 Contraindications

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

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

Safety in pregnancy and lactation has not been established.

4.4 Special warnings and precautions for use

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 THROAT SPRAY 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.

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

CHLORZYD ANTISEPTIC THROAT SPRAY is not compatible with anionic agents which are usually present in conventional dentifrices, including toothpaste. These should therefore be used before CHLORZYD ANTISEPTIC THROAT SPRAY (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 THROAT SPRAY 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 3000 mg sorbitol in each 30 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 medicines for oral use may affect the bioavailability of other medicines for oral use administered concomitantly.

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

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 use of CHLORZYD ANTISEPTIC THROAT SPRAY.

4.6 Fertility, pregnancy and lactation

The safety of CHLORZYD ANTISEPTIC THROAT SPRAY in pregnancy and lactation has not been established (see section 4.3).

While propylene glycol has not been shown to cause reproductive or developmental toxicity in animals or humans, it may reach the foetus and was found in milk.

4.7 Effects on ability to drive and use machines

CHLORZYD ANTISEPTIC THROAT SPRAY has no or negligible influence on the patient's ability to drive or use machines.

4.8 Undesirable effects

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, angioedema which may include swelling of the face, lips, tongue and/or throat, and which may be potentially life-threatening
Nervous system disorders	*Frequent*	Aguesia / dysguesia, glossodynia, oral paraesthesia/ hypoaesthesia

System Organ Class	Frequency	Adverse reaction
Respiratory, thoracic and mediastinal disorders	*Less frequent*	Laryngospasm or bronchospasm
Gastrointestinal disorders	*Frequent*	Tongue coated, dry mouth
	Less frequent	Oral numbness (hypothesia) and a stinging feeling in the mouth (oral pain), dryness or thirst, reversible discolouration of the tongue and teeth, transient disturbance of taste, oral desquamation, swelling of the parotid gland
	Frequency unknown	Gastro-intestinal disturbances, irritation of the mouth

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.

Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za. By reporting side effects, you can help provide more information on the safety of CHLORZYD ANTISEPTIC THROAT SPRAY.

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

36 months.

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 THROAT SPRAY is packed in a white HDPE bottle with a spray applicator and the secondary package material is carton box.

30 ml

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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enquiries@unicornpharma.co.za

8. REGISTRATION NUMBER(S)

53/16.4/0607

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 March 2024

10. DATE OF REVISION OF THE TEXT

Not applicable