PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

GESORAL ORAL SPRAY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains 22,5 mg benzydamine hydrochloride and 18,0 mg chlorhexidine gluconate.

GESORAL ORAL SPRAY contains alcohol: 9,1 % *v/v*

GESORAL ORAL SPRAY contains sugar, sorbitol: 3 g/15 mL.

GESORAL ORAL SPRAY contains sweetener, sodium saccharin 1,5 mg/mL

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral spray.

GESORAL ORAL SPRAY is a clear pinkish-red solution with a minty taste and odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

throat.

Chlorhexidine in GESORAL ORAL SPRAY helps to reduce the development of plaque

4.2 Posology and method of administration

Posology

Adults and children over 12 years

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

Paediatric population

Not indicated for use in children under 12 years of age.

Method of administration

For oral administration. Shake bottle before use. Avoid contact with the eyes.

4.3 Contraindications

- hypersensitivity to benzydamine, chlorhexidine or to any of the ingredients of GESORAL ORAL SPRAY (see section 6.1)
- children under 12 years of age
- pregnancy and lactation.

4.4 Special warnings and precautions for use

Benzydamine (as in GESORAL ORAL SPRAY) use is not advisable in patients with

hypersensitivity to acetylsalicylic acid or other NSAIDs.

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

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.

If the condition is aggravated or not improved, use should cease.

GESORAL ORAL SPRAY contains sorbitol which is a source of fructose.
Sorbitol may cause gastrointestinal discomfort and a mild laxative effect.
Patients with hereditary fructose intolerance (HFI) must not be given this medicine.
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.
GESORAL ORAL SPRAY contains a small amount of alcohol (see section 2), equivalent to less than 30 mL beer or 12 mL wine. This small amount of alcohol will not have any noticeable effects.

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Paediatric population

Not suitable for children aged 12 years or under (see section 4.3).

4.5 Interaction with other medicines and other forms of interaction

Anionic surfactants (contained in 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 using GESORAL ORAL SPRAY administration.

4.6 Fertility, pregnancy and lactation

The safety of GESORAL ORAL SPRAY in pregnancy and lactation has not been established (see section 4.3).

Pregnancy

From the 20th week of pregnancy onward, benzydamine may cause oligohydramnios resulting from foetal renal dysfunction. This may occur shortly after treatment initiation and is usually reversible upon discontinuation. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment cessation. Therefore, during the first and second trimester of pregnancy, GESORAL ORAL SPRAY should not be used unless clearly necessary. If GESORAL ORAL SPRAY is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible. Antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be

considered after exposure to benzydamine for several days from gestational week 20 onward. GESORAL ORAL SPRAY should be discontinued if oligohydramnios or ductus arteriosus constriction are found. During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- cardiopulmonary toxicity (premature constriction/closure of the ductus arteriosus and pulmonary hypertension)
- renal dysfunction (see above)

the mother and the neonate, at the end of pregnancy, to:

- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, GESORAL ORAL SPRAY is contraindicated during the third trimester of pregnancy (see sections 4.3).

Breastfeeding

GESORAL ORAL SPRAY is contraindicated during the third trimester of pregnancy (see sections 4.3).

Fertility

There is no data on fertility with GESORAL ORAL SPRAY.

4.7 Effects on ability to drive and use machines

GESORAL ORAL SPRAY has no or negligible influence on the ability to drive and use machines.

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4.8 Undesirable effects

Summary of the safety profile

The most common side effects are numbness and a stinging feeling in the mouth.

Tabulated list of adverse effects

System Organ Class	Frequency	Side effects
Immune system disorders	Less frequent	Hypersensitivity reactions including urticaria, rash, bronchospasm, or laryngospasm and photodermatitis
	Frequency unknown	Serious allergic reaction (anaphylactic shock) which may be potentially life-threatening, 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, and which may be potentially life-threatening
Respiratory, thoracic and mediastinal disorders	Less frequent	Laryngospasm, bronchospasm

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Gastrointestinal disorders	Less frequent Frequency unknown	Oral tissue numbness and a stinging feeling in the mouth. The stinging has been reported to disappear upon continuation of the treatment, however if it persists it is recommended that treatment be discontinued. Gastro-intestinal disturbances
Skin and subcutaneous tissue disorders	Less frequent Frequency unknown	Pruritus, urticaria, photosensitivity reaction and rash Angioedema
General disorders and administrative site conditions	Less frequent	Dryness or thirst, reversible discolouration of the tongue and teeth, transient disturbances 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 professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

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4.9 Overdose

Signs and symptoms:

Most frequent gastrointestinal symptoms are nausea, vomiting, sore throat and abdominal pain. Symptoms of the central nervous system include dizziness, hallucinations, agitation, anxiety, and irritability.

Management of overdose:

There is no specific antidote for benzydamine. Treatment should be symptomatic and supportive. Adequate hydration must be maintained.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other anti-inflammatory and antirheumatic agents, non-steroids /Anti-inflammatory preparations, non-steroids for topical use.

ATC code: M01AX07

Pharmacological classification: A 16.4 Nasopharyngeal and bucco-pharyngeal antiseptics

Mechanism of action

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

Absorption:

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Benzydamine:

When administered as a local application, benzydamine has a low systemic absorption which reduces the potential of systemic side effects.

Chlorhexidine:

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

Biotransformation:

Benzydamine:

Metabolism is mainly through oxidation, dealkylation and conjugation.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colour carmoisine

Ethyl alcohol 96 %

Flavour peppermint

Glycerine

Poloxamer P 407

Purified water

Sodium saccharin

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Sorbitol 70 % non-crystallizing solution

6.2 Incompatibilities

Not applicable.

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

30 ml round clear flint Type III glass bottle with plastic spray pump protected with a clear polypropylene clip-on cap. A polypropylene actuator (spray tube) enclosed in a plastic sleeve in the carton, is to be fitted onto the pump.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER(S)

A48/16.4/0942

9. DATE OF FIRST AUTHORISATION

23 August 2022

10. DATE OF REVISION OF THE TEXT

03 March 2025