PROFESSIONAL INFORMATION

GESORAL

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).

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

4.6 Fertility, pregnancy and lactation

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

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.

4.8 Undesirable effects

a). Summary of the safety profile

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

b). Tabulated summary of adverse reactions

System Organ Class	**Frequency**	**Side effects**

Immune system disorders	Less frequent Frequency unknown	Hypersensitivity reactions including urticaria, rash, bronchospasm or laryngospasm and photodermatitis 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.
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 asked to report any suspected adverse reactions to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8.
An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

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.

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:

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colour carmoisine

Alcohol

Flavour peppermint

Glycerine

Poloxamer P 407

Purified water

Sodium saccharin

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 inside 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

Pharma Dynamics (Pty) Ltd

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8. REGISTRATION NUMBER

A48/16.4/0942

9. DATE OF FIRST AUTHORISATION

23 August 2022

10. DATE OF REVISION OF THE TEXT

April 2023