

GESORAL ORAL SPRAY

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 % w/v
GESORAL ORAL SPRAY contains sugar, sorbitol: 3 g/15 mL
GESORAL ORAL SPRAY contains sweetener, sodium saccharin: 1,5 mg/15 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	<i>Less frequent</i>	Hypersensitivity reactions including urticaria, rash, bronchospasm or laryngospasm and photodermatitis
	<i>Frequency unknown</i>	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	<i>Less frequent</i>	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
	<i>Frequency unknown</i>	Gastro-intestinal disturbances
Skin and subcutaneous tissue disorders	<i>Less frequent</i>	Pruritus, urticaria, photosensitivity reaction and rash
	<i>Frequency unknown</i>	Angioedema
General disorders and administrative site conditions	<i>Less frequent</i>	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 buccopharyngeal 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, supplied additionally in the outer carton, is fitted on the pump.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

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Silverwood Close
Westlake, Cape Town
7945, South Africa

8. REGISTRATION NUMBER

A48/16.4/0942

9. DATE OF FIRST AUTHORISATION

23 August 2022

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S1

GESORAL ORAL SPRAY

Benzydiamine hydrochloride and Chlorhexidine gluconate
GESORAL ORAL SPRAY contains sugar, sorbitol 3 g/15 mL

GESORAL ORAL SPRAY contains alcohol 9,1 % w/v
GESORAL ORAL SPRAY contains sweetener, sodium saccharin 1,5 mg/15 mL

Read all of this leaflet carefully because it contains important information for you

- GESORAL ORAL SPRAY is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use GESORAL ORAL SPRAY carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share GESORAL ORAL SPRAY with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

- What GESORAL ORAL SPRAY is and what it is used for
- What you need to know before you use GESORAL ORAL SPRAY
- How to use GESORAL ORAL SPRAY
- Possible side effects
- How to store GESORAL ORAL SPRAY
- Contents of the pack and other information

1. What GESORAL ORAL SPRAY is and what it is used for

GESORAL ORAL SPRAY contains the active substances benzylidiamine hydrochloride, which belongs to a group of medicines called non-steroidal anti-inflammatory medicines (NSAIDs), and chlorhexidine gluconate which is an antiseptic medicine.

GESORAL ORAL SPRAY is used for the relief of minor infections and painful inflammatory conditions of the mouth and throat and helps to reduce the development of plaque.

2. What you need to know before you use GESORAL ORAL SPRAY

Do not use GESORAL ORAL SPRAY:

- if you are hypersensitive (allergic) to benzylidiamine, chlorhexidine, or to any of the ingredients of GESORAL ORAL SPRAY (see section 6)
- in children under 12 years of age
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with GESORAL ORAL SPRAY:

- if you are allergic to acetylsalicylic (aspirin) acid or other NSAIDs
- if you have asthma
- your treatment should not last longer than 7 days without medical supervision
- if your symptoms become worse when using GESORAL ORAL SPRAY.

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

Other medicines and GESORAL ORAL SPRAY

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Toothpastes may contain cleaning ingredients which are incompatible with chlorhexidine. It is recommended that you wait at least 30 minutes between brushing your teeth and using GESORAL ORAL SPRAY.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using GESORAL ORAL SPRAY. You should not use GESORAL ORAL SPRAY if you are pregnant or breastfeeding your baby.

Driving and using machines

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

It is not always possible to predict to what extent GESORAL ORAL SPRAY may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GESORAL ORAL SPRAY affects them.

GESORAL ORAL SPRAY contains sorbitol

Sorbitol is a source of fructose. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HF), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. GESORAL ORAL SPRAY contains a small amount of alcohol.

3. How to use GESORAL ORAL SPRAY

Always use GESORAL ORAL SPRAY exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Adults and children over 12 years:

Shake bottle before use.
The usual dose is 5 to 10 sprays directly onto the painful or inflamed area and swallow gently. Repeat every 1½ to 3 hours as necessary.

Avoid contact with the eyes. Should GESORAL ORAL SPRAY come into contact with the eyes, rinse thoroughly with water.

Children:

GESORAL ORAL SPRAY is not indicated for use in children 12 years and younger.

You should not use GESORAL ORAL SPRAY for longer than 7 days without medical supervision.

How to clean and care for GESORAL ORAL 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 medicine 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.

If you use more GESORAL ORAL SPRAY than you should in the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- nausea and vomiting
- sore throat
- abdominal pain
- dizziness
- hallucinations
- agitation
- anxiety
- irritability.

If you forget to use GESORAL ORAL SPRAY

If you forget to use GESORAL ORAL SPRAY, take as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

GESORAL ORAL SPRAY can have side effects.

Not all side effects reported for GESORAL ORAL SPRAY are included in this leaflet. Should your general health worsen, or if you experience any unwanted effects while using GESORAL ORAL SPRAY, please consult your healthcare provider for advice.

If any of the following happens, stop using GESORAL ORAL SPRAY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to GESORAL ORAL SPRAY. You may need urgent medical attention or hospitalisation.

Bestuur en die hantering van masjiene

GESORAL ORAL SPRAY het geen, of 'n onbeduidende invloed op die vermoë om te bestuur of masjiene te hanter. Dit is nie altyd moontlik om te voorspel tot watter mate GESORAL ORAL SPRAY met die daaglikse aktiwiteite van 'n pasiënt sal inmeng nie. Pasiënte moet versker dat hulle nie by bogemede aktiwiteite betrokke raak, totdat hulle weet hoe GESORAL ORAL SPRAY hulle aantas nie.

GESORAL ORAL SPRAY bevat sorbitol

Sorbitol is 'n bron van fruktose. Sorbitol mag gastrointestinale ongemak veroorsaak en 'n ligte lakserende uitwerking toon. Indien u dokter aangedui het dat u (of u kind), 'n onverdraagsaamheid teenoor sommige suikers toon, of u gedragseer is met owerflieke fruktose onverdraagsaamheid (OFD) 'n skaars genetiese versteuring, waar 'n persoon nie fruktose kan verwerk nie, praat met u dokter voordat u (of u kind) hierdie medisyne neem, of gebruik. GESORAL ORAL SPRAY bevat 'n klein hoeveelheid alkohol.

3. Hoe om GESORAL ORAL SPRAY te gebruik

Gebruik GESORAL ORAL SPRAY altyd presies soos in hierdie inligtingsblad aangedui word, of soos deur u dokter, apteker of verpleegkundige aangewys word. Raadpleeg u dokter, apteker, of verpleegkundige indien u onseker is.

Volwasse en kinders ouer as 12 jaar: In die gewone dosis is 5 tot 10 sproei, direk op die pylneke of onsteekte oppervlakte en sluk versigtig. Herhaal elke 1½ tot 3 uur, soos benodig word.

Vermi kontak met die oë. Sou GESORAL ORAL SPRAY in kontak met die oë kom, spoel deeglik uit met water.

Kinders: GESORAL ORAL SPRAY word nie aangedui vir gebruik deur kinders 12 jaar oud en jonger nie.

U moet nie GESORAL ORAL SPRAY vir langer as 7 dae gebruik, sonder mediese toesig nie.

Hoe om GESORAL ORAL SPRAY skoon te maak en te versorg:

- Spoel die toedienerspil en die tuil na elke gebruik af om sporadiese blokkasies van die sproeibuis te voorkom.
- Spoel die sproeibuis af in warm, lopende water vir ten minste 30 sekondes en laat die water toe om deur die sproeibuis te loop. Dit is baie belangrik, aangesien die klein opening wat die medisyne voorsien, somtyds blokkeer mag word.
- Skud die oormaat water af en laat die sproeibuis heeltemal droog word.

Note: blokkade weens die opbou van medisyne, sal meer waarsynlik voorkom, indien die buis nie volkome droog is nie. Die sproei moet in 'n regop posisie bewaar word.

Indien u meer GESORAL ORAL SPRAY gebruik as wat u behoort

Indien die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal, of gifbeheersentrum.

Simptome van oordosering, mag die volgende insluit:

- onbehoedende braking
- seer keel
- abdominale pyn
- duiseligheid
- halusinasies
- agitasie
- angstigtheid
- prinkelbaarheid.

Indien u vergeet om GESORAL ORAL SPRAY te gebruik

Indien u vergeet om GESORAL ORAL SPRAY te gebruik, gebruik dit so gou as wat u onthou. Moet nie 'n dubbeldosis neem om op te maak vir die vergele, individuele doserings nie.

4. Moontlike nuwe-effekte

GESORAL ORAL SPRAY kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir GESORAL ORAL SPRAY aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongewenste effekte ervaar, verwys u GESORAL ORAL SPRAY gebruik, raadpleeg asseblief u gesondheidsorgverreker vir advies.

Indien enige van die volgende gebeur, staak die gebruik van GESORAL ORAL SPRAY en vertel u dokter onmiddellik, of gaan na die ongevalleafdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk of asemhaling mag bemoeilik
- uitslag of geuk.

Hierdie is alles baie ernstige nuwe-effekte. Indien u dit het, kon u 'n ernstige allergiese reaksie met GESORAL ORAL SPRAY gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

Tell your doctor if you notice any of the following:
Less frequent side effects:

- mouth numbness, stinging feeling in the mouth
- skin rash, itching, a rash of round, red welts (hives), sensitivity to sunlight
- dryness of the mouth, thirst, reversible discolouration of the tongue and teeth, changes in taste, peeling of the skin inside the mouth, swelling of the salivary glands

The following side effects have been reported but the frequency for them to occur is not known:

- gastrointestinal disturbances such as stomach pain, heartburn, diarrhoea, constipation
- swelling under the skin (angioedema).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of GESORAL ORAL SPRAY. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store GESORAL ORAL SPRAY

Store all medicines out of reach of children. Store in the carton, at or below 30 °C, in an upright position.

Protect from light.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GESORAL ORAL SPRAY contains

Each 15 mL contains 22.5 mg benzylidiamine hydrochloride and 18,0 mg chlorhexidine gluconate. GESORAL ORAL SPRAY contains alcohol 9,1 % w/v GESORAL ORAL SPRAY contains sorbitol: 3 g/15 mL GESORAL ORAL SPRAY contains sweetener, sodium saccharin: 1,5 mg/15 mL

The other ingredients are: Colour carmoisine, alcohol, flavour peppermint, glycerine, poloxamer P 407, purified water, sodium saccharin, sorbitol 70 % non-crystallizing solution.

What GESORAL ORAL SPRAY looks like and contents of the pack

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

GESORAL ORAL SPRAY is available in a 30 mL round clear flint Type III glass bottle with plastic spray pump protected with a clear polypropylene clip-on cap. A polypropylene actuator, supplied additionally in the outer carton, is fitted on the pump.

Holder of Certificate of Registration

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PASIENTINLIGTINGSBLAD

SKEDULERINGSSTATUS S1

GESORAL ORAL SPRAY

Bensidiamienhidrochloried en Chloorheksidiengluconaat
GESORAL ORAL SPRAY bevat suiker, sorbitol 3 g/15 mL
GESORAL ORAL SPRAY bevat alkohol 9,1 % w/v
GESORAL ORAL SPRAY bevat die versoeter, natriumsakkarine 1,5 mg/15 mL

Lees hierdie hele inligtingsblad deeglik deur, want dit bevat belangrike inligting vir u

- GESORAL ORAL SPRAY is beskikbaar vir u sonder 'n dokter se voorskrif, om 'n minder ernstige siekte te behandel. U moet nie met GESORAL ORAL SPRAY omsigtig gebruik, om die beste resultate daarvan te verkry.
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Moet nie GESORAL ORAL SPRAY met enige ander persoon deel nie.
- Vra u gesondheidsorgverreker of apteker, indien u meer inligting of advies benodig.

Wat hierdie inligtingsblad bevat

- Wat GESORAL ORAL SPRAY is en waarvoor dit gebruik word
- Wat u nodig het om te weet, voordat u GESORAL ORAL SPRAY gebruik
- Hoe om GESORAL ORAL SPRAY te gebruik
- Moontlike nuwe-effekte
- How to store GESORAL ORAL SPRAY te bewaar
- Verpakkingsinhoud en ander inligting

1. Wat GESORAL ORAL SPRAY is en waarvoor dit gebruik word

GESORAL ORAL SPRAY bevat die aktiewe bestanddele bensidiamienhidrochloried, wat aan 'n groep medisyne wat nie-steroidale anti-inflammatoriese medisyne (NSAID) genoem word, behoort en chloorheksidiengluconaat, wat 'n antiseptiese medisyne is.

GESORAL ORAL SPRAY word gebruik vir die verligting van minder ernstige infeksies en pylneke inflammatoriese toestande van die mond en keel en help om die vorming van plak te verminder.

2. Wat u nodig het om te weet, voordat u GESORAL ORAL SPRAY gebruik

Moet nie GESORAL ORAL SPRAY gebruik:

- indien u hipersensitief (allergies) is vir bensidiamien, chloorheksidien, of vir enige van die bestanddele van GESORAL ORAL SPRAY nie
- deur kinders jonger as 12 jaaroud nie
- indien u swanger is of borsvoed nie.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met GESORAL ORAL SPRAY:

- indien u allergies is vir asetielsalisiesuur (aspien), of ander NSAIDs
- indien u aan asma ly
- u behandeling moet nie langer as 7 dae, sonder mediese toesig, duur nie
- indien u simptome vererger terwyl u GESORAL ORAL SPRAY gebruik.

Vermi kontak met die oë. Sou dit in kontak met die oë kom, was dit deeglik uit met water.

Ander medisyne en GESORAL ORAL SPRAY

Vertel altyd u gesondheidsorgverreker indien u enige ander medisyne neem. (Dit sluit aanvallende of tradisionele medisyne in).

Tandepasta mag skoonmaakbestanddele bevat, wat onverenigbaar met chloorheksidien mag wees. Daar word aanbeveel dat u ten minste 30 minute wag, tussen tandeborsel en die gebruik van GESORAL ORAL SPRAY.

Swangerskap, borsvoeding en fertiliteit

Indien u swanger is, of u baba borsvoed, vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverreker vir advies, voordat u GESORAL ORAL SPRAY gebruik. U moet nie GESORAL ORAL SPRAY gebruik, indien u swanger is of u baba borsvoed nie.

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