PATIENT INFORMATION LEAFLET

GESORAL ORAL SPRAY

SCHEDULING STATUS

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GESORAL ORAL SPRAY

Benzydamine hydrochloride and Chlorhexidine gluconate

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

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

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

Read all of this leaflet carefully before you start using GESORAL ORAL SPRAY

- 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

1. What GESORAL ORAL SPRAY is and what it is used for
2. What you need to know before you use GESORAL ORAL SPRAY
3. How to use GESORAL ORAL SPRAY
4. Possible side effects
5. How to store GESORAL ORAL SPRAY
6. 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 benzydamine 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 take GESORAL ORAL SPRAY

Do not take GESORAL ORAL SPRAY:

- if you are hypersensitive (allergic) to benzydamine, 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 (HFI), 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. Fit the actuator on the pump.

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 spray:

1. Rinse the actuator (spray tube) after every use to avoid sporadic blockages of the spray tube.
2. 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.
3. 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 untoward 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.

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 or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report 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.

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

By reporting side effects, you can help provide more information on the safety of GESORAL ORAL SPRAY

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 benzydamine hydrochloride and 18,0 mg chlorhexidine gluconate.

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

GESORAL ORAL SPRAY contains Sorbitol: 3,75 g/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 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.

Holder of Certificate of Registration

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