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## **DEVATIS SORE THROAT RELIEF GARGLE**

**DEVATIS**

*Oral solution containing Benzydamine hydrochloride 0.15% w/v and Chlorhexidine gluconate 0.12% w/v*

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## **CONSUMER MEDICINE INFORMATION (CMI)**

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### **WHAT IS IN THIS LEAFLET**

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**Please read this leaflet carefully before you start using DEVATIS SORE THROAT RELIEF GARGLE.**

This leaflet answers some common questions about DEVATIS SORE THROAT RELIEF GARGLE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using DEVATIS SORE THROAT RELIEF GARGLE against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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### **WHAT DEVATIS SORE THROAT RELIEF GARGLE IS USED FOR**

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DEVATIS SORE THROAT RELIEF GARGLE contains the active ingredients benzydamine hydrochloride and chlorhexidine gluconate.

Benzydamine hydrochloride belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). They work to reduce pain and inflammation in the body. Benzydamine hydrochloride also possesses local anesthetic activity to further enhance pain relief.

Chlorhexidine gluconate is an antiseptic agent that kills or prevents the growth of a wide range of bacteria that may be involved in causing pain and inflammation in conditions of the mouth and throat.

DEVATIS SORE THROAT RELIEF GARGLE is used for relief of painful conditions of the throat and mouth.

DEVATIS SORE THROAT RELIEF GARGLE may also be used to relieve of pain following throat surgery, or following dental procedures.

**Ask your pharmacist or doctor if you have any questions about this medicine.**

Your pharmacist or doctor may have given DEVATIS SORE THROAT RELIEF GARGLE for another reason. Ask your doctor if you have any questions about why DEVATIS SORE THROAT RELIEF GARGLE has been given to you.

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## BEFORE YOU USE DEVATIS SORE THROAT RELIEF GARGLE

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### *When you must not use it*

**Do not use DEVATIS SORE THROAT RELIEF GARGLE if you have an allergy to:**

- any medicine containing Benzydamine hydrochloride, Chlorhexidine gluconate
- any of the ingredients listed at the end of this leaflet.

Some of symptoms of an allergic reaction may include:

- shortness of breath,
- skin rash,
- swelling of the face and/or tongue.

**Do not use this medicine if you are pregnant or breastfeeding.**

**Do not take this medicine after the expiry date printed on the pack and blister.**

The expiry date is printed on bottle and box after “EXP” (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

**Do not take this medicine if the packaging is torn or shows signs of tampering.**

**If you are not sure whether you should start taking DEVATIS SORE THROAT RELIEF GARGLE, talk to your pharmacist or doctor.**

### *Before you start to use it*

**Tell your pharmacist or doctor if you have or have had any of the following medical conditions:**

- kidney and liver problems

**If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking DEVATIS SORE THROAT RELIEF GARGLE.**

### *Taking other medicines*

**Tell your pharmacist or doctor if you are taking any other medicines, including any that you get without a prescription or that are herbal from your pharmacy, supermarket or health food shop.**

You should also tell any health professional who is prescribing a new medication for you that you are taking DEVATIS SORE THROAT RELIEF GARGLE.

DEVATIS SORE THROAT RELIEF GARGLE does not have known significant drug interaction. Chlorhexidine salts, one of the drug substances in DEVATIS SORE THROAT RELIEF GARGLE, are incompatible with soap and other negatively charged (anionic) compounds, chloramphenicol (type of antibiotic), some inorganic salts and organic compounds. Drug interaction with benzydamine has not been reported. Alcohol interaction is none known.

Your pharmacist or doctor will have more information on medicines to be careful with or avoid while taking DEVATIS SORE THROAT RELIEF GARGLE.

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## HOW TO USE DEVATIS SORE THROAT RELIEF GARGLE

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**Follow all directions on the label or those given to you by your pharmacist or doctor carefully. If you do not understand the instructions on the label, ask your pharmacist or doctor for help.**

### *How much to use*

**Adults:** Rinse or gargle with 15 ml every 1.5 to 3 hours, four times a day at most. Hold the solution in the mouth for at least 30 seconds.

**Adolescents** (12 years of age and above): Rinse or gargle with 5-15 ml every 1.5 to 3 hours, four times a day at most. Hold the solution in the mouth for at least 30 seconds.

### *How to use it*

DEVATIS SORE THROAT RELIEF GARGLE is used as either a mouth rinse or a gargle. Best used undiluted, however, should be diluted with water if stinging or burning occurs.

Do not swallow DEVATIS SORE THROAT RELIEF GARGLE and spit out after each use. Thoroughly brush teeth before use to minimize the risk of discoloring the teeth.

DEVATIS SORE THROAT RELIEF GARGLE should not be used for more than 7 days.

### *When to use it*

Apply your medicine every 1.5-3 hours, four times a day at most.

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## WHILE YOU ARE USING DEVATIS SORE THROAT RELIEF GARGLE

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### *Things you must do*

**Use DEVATIS SORE THROAT RELIEF GARGLE exactly as your doctor or pharmacist has prescribed.**

**Tell all doctors, dentists and pharmacists who are treating you that you are using DEVATIS SORE THROAT RELIEF GARGLE.**

**Talk to your pharmacist or doctor if your symptoms do not improve.**

In the case of sore throats, if symptoms do not improve after a few days of treatment, consult your doctor as the condition may require treatment with antibiotics.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking DEVATIS SORE THROAT RELIEF GARGLE.

### *Things you must not do*

**Do not use DEVATIS SORE THROAT RELIEF GARGLE to treat any other complaints unless your pharmacist or doctor tells you to.**

**Do not give DEVATIS SORE THROAT RELIEF GARGLE to anyone else, even if they have the same condition as you.**

**Do not use more than the recommended dose unless your pharmacist or doctor tells you to.**

**Do not use this medicine in children under 12 years of age.**

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***Things to be careful of***

- For external use only.
- For use in the mouth and throat.
- Do not swallow DEVATIS SORE THROAT RELIEF GARGLE and spit out after each use.
- It may cause reversible color change in mouth, on tongue and teeth. Tooth-brushing is recommended before application to minimize discoloration.

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**IN CASE OF OVERDOSE**

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***If you use too much (overdose)***

**Immediately telephone your doctor, pharmacist or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too much DEVATIS SORE THROAT RELIEF GARGLE. Do this even if there are no signs of discomfort or poisoning.**

If DEVATIS SORE THROAT RELIEF GARGLE is accidentally swallowed, your doctor will institute symptom-oriented treatment.

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**SIDE EFFECTS**

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**Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using DEVATIS SORE THROAT RELIEF GARGLE.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your pharmacist or doctor to answer any questions you may have.**

**Tell your pharmacist or doctor if you notice any of the following and they worry you:**

- Numbness in mouth tissue
- Tingling and burning sensation in the mouth
- Dizziness, headache, drowsiness
- Nausea, vomiting, retching
- Dry mouth or thirst
- Feeling of coolness in the mouth
- Altered taste
- Staining of teeth and other oral surfaces
- Increase in tartar formation

These are mild side effects of DEVATIS SORE THROAT RELIEF GARGLE. These side effects disappear when the dose is reduced or when the treatment is stopped.

**Tell your pharmacist or doctor as soon as possible if you notice any of the following:**

- Irritation-associated skin reactions
- Mouth rash
- Irritation in throat and coughing
- Growth of salivary gland

These are serious side effects. Urgent medical attention may be required. These serious side effects occur very rarely.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Sudden shortness of breath, skin rash, swelling of face and/or tongue.
- Hypersensitivity reactions
- Allergic reaction

These are very serious side effects. If you experience any of these side effects, it indicates that you have serious allergy to DEVATIS SORE THROAT RELIEF GARGLE. If you experience any of these, you may need urgent medical attention or hospitalization.

These very serious side effects occur very rarely.

**Tell your pharmacist or doctor if you notice anything that is making you feel unwell.**

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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## AFTER USING DEVATIS SORE THROAT RELIEF GARGLE

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### *Storage*

**Keep out of the reach and sight of children.**

Store at or below 25°C and protect from light.

### *Disposal*

**Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.**

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## PRODUCT DESCRIPTION

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### *What it looks like*

DEVATIS SORE THROAT RELIEF GARGLE is a colorless to yellowish colored, clear solution with peppermint odor.

DEVATIS SORE THROAT RELIEF GARGLE is presented in a 200 ml, amber colored glass bottle closed with 28 mm child-resistant, tamper evident polypropylene screw cap with an induction activated polyethylene liner.

### *Ingredients*

#### Active ingredient(s):

DEVATIS SORE THROAT RELIEF GARGLE contains benzydamine hydrochloride and chlorhexidine gluconate.

Each 15 ml dose contains 22.5 mg benzydamine hydrochloride (0.15% w/v) and 18 mg chlorhexidine gluconate (0.12% w/v).

#### Inactive ingredients:

The other ingredients are saccharin sodium, glycerine, polysorbate 20, alcohol (ethanol 96%), purified water, peppermint flavor, sodium hydrogen carbonate/HCl (for pH adjustment).

Contains alcohol (17.25% w/v).

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## SPONSOR

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DEVATIS LIMITED  
45 Yarrow Street,  
Invercargill 9810, New Zealand



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Tel: +64 3 211 0080  
Fax: +64 3 211 0079  
[www.devatis.nz](http://www.devatis.nz)

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## **DATE OF PREPARATION**

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This leaflet was revised in October 2021.