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## DEVATIS SORE THROAT RELIEF SPRAY

## DEVATIS

Oral spray 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 SPRAY.**

This leaflet answers some common questions about DEVATIS SORE THROAT RELIEF SPRAY. 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 SPRAY 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 SPRAY IS USED FOR

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DEVATIS SORE THROAT RELIEF SPRAY 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 SPRAY is used for relief of painful conditions of the throat.

DEVATIS SORE THROAT RELIEF SPRAY 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 SPRAY for another reason.

Ask your doctor if you have any questions about why DEVATIS SORE THROAT RELIEF SPRAY has been given to you.

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#### BEFORE YOU USE DEVATIS SORE THROAT RELIEF SPRAY

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*When you must not use it*

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

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

*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 SPRAY.

DEVATIS SORE THROAT RELIEF SPRAY does not have known significant drug interaction.

Chlorhexidine salts, one of the drug substances in DEVATIS SORE THROAT RELIEF SPRAY, 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 this medicine.

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## HOW TO USE DEVATIS SORE THROAT RELIEF SPRAY

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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** >18 years: 5-10 sprays directly onto sore/inflamed area. Repeat every 1.5-3 hours, four times a day at most.

**Adolescents** (above 12 years of age): 5 sprays directly onto sore/inflamed area. Repeat every 1.5-3 hours, four times a day at most.

### *How to use it*

**Do not swallow DEVATIS SORE THROAT RELIEF SPRAY and spit out any remaining product after administration of the total number of sprays required.**

- The first time you use the spray you need to prime it. Point the spray-tube away from your face. Press down firmly on the white plunger until a fine spray appears from the end of the spray-tube. The spray is now ready to use.
- Aim the spray-tube at the sore part of your throat and press down on the white plunger again. One press releases one puff.
- Thoroughly brush teeth before use to minimize the risk of discoloring the teeth.

### *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 SPRAY**

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### *Things you must do*

**Use DEVATIS SORE THROAT RELIEF SPRAY 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 SPRAY.**

**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 SPRAY.

### *Things you must not do*

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

**Do not give DEVATIS SORE THROAT RELIEF SPRAY 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.**

### *Things to be careful of*

- This is a spray for the use in the throat.
- Keep out of the eyes and ears.
- In case of contact with eyes/ears, rinse immediately with plenty of water and seek medical advice.
- **Do not swallow DEVATIS SORE THROAT RELIEF SPRAY and spit out any remaining product after administration of the total number of sprays required.**
- 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 SPRAY. Do this even if there are no signs of discomfort or poisoning.**

If DEVATIS SORE THROAT RELIEF SPRAY 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 SPRAY.**

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 SPRAY. 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 SPRAY.

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 SPRAY

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### *Storage*

Keep out of the reach and sight of children, to mitigate the risk of accidental ingestion resulting in adverse symptoms of intoxication by children.

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

Store in an upright position.

### *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 SPRAY is a colorless to yellowish colored, clear solution with peppermint odor.

DEVATIS SORE THROAT RELIEF SPRAY is presented in a 30 ml, amber colored glass bottle with a plastic spray pump and polypropylene applicator.

### *Ingredients*

#### Active ingredient(s):

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

Each spray delivers 0.21 mg benzydamine hydrochloride (0.15% w/v) and 0.168 mg chlorhexidine gluconate (0.12% w/v).

214 sprays per bottle (30 ml).

#### 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 (34.5 % w/v).

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## SPONSOR

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## DATE OF PREPARATION

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This leaflet was revised in October 2021.