NEW ZEALAND DATA SHEET

1. PRODUCT NAME

DEVATIS SORE THROAT RELIEF SPRAY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
DEVATIS SORE THROAT RELIEF SPRAY contains benzydamine hydrochloride and chlorhexidine gluconate.
Each spray delivers 0.195 mg benzydamine hydrochloride (0.15% w/v) and 0.156 mg chlorhexidine gluconate (0.12% w/v).

Excipient with known effect:
Contains alcohol (34.5 % w/v).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
It is used for mouth and throat antisepsis, for relief of patient's swallowing function and as symptom reliever in gingival diseases. It can be used for prophylaxis before dental procedures.

4.2 Posology and method of administration
The usual dose of DEVATIS SORE THROAT RELIEF SPRAY is 5-10 sprays for its direct application onto throat/inflamed area. It is repeated every 1.5-3 hours as necessary.

Method of administration
DEVATIS SORE THROAT RELIEF SPRAY is used without dilution. DEVATIS SORE THROAT RELIEF SPRAY should not be swallowed and should be expectorated after each use.

Before the initial use, it should be directed into an area away from the face and pumping button should be pressed couple of times until a fine spray is obtained.

Mouth should be wide opened; spray nozzle should be put inside the mouth and sprayed into the oral cavity. This procedure should be repeated at different areas at least for 4 times.

After application, bottle should be placed inside its box and kept in upright position.
Chlorhexidine in DEVATIS SORE THROAT RELIEF SPRAY reduces plaque and gingivitis during treatment. If DEVATIS SORE THROAT RELIEF SPRAY is used as an alternative to oral hygiene procedures, DEVATIS SORE THROAT RELIEF SPRAY should be hold in the mouth for at least 1 minute.

Teeth should be brushed before use in order to minimize the discoloration induced by chlorhexidine in DEVATIS SORE THROAT RELIEF SPRAY.

Additional information on special population

Renal/Hepatic impairment
As absorbed benzydamine is highly metabolized in the liver, the possibility of systemic effect should be taken into consideration in patients with severe hepatic impairment.
As absorbed benzydamine and its metabolites are excreted in the urine, the possibility of systemic effect should be taken into consideration in patients with severe renal impairment.

Adolescents
In adolescents aged over 12 years, spray is directly applied to throat/inflamed area. The usual dose is 5 sprays. It is repeated every 1.5-3 hours as necessary.

Due to insufficient number of clinical studies, DEVATIS SORE THROAT RELIEF SPRAY is not recommended for children under 12 years of age (see section 4.4).

Geriatric population
The same dose as adults can be applied to geriatric patients.

4.3 Contraindications
It is contraindicated in patients with hypersensitivity to benzydamine and chlorhexidine and any of the ingredients in DEVATIS SORE THROAT RELIEF SPRAY.
It should not be used during pregnancy and lactation.

4.4 Special warnings and precautions for use
- For external use.
- Due to insufficient number of clinical studies, DEVATIS SORE THROAT RELIEF SPRAY is not recommended for children under 12 years of age.
- It is used only in the mouth; its contact with eyes and ears should be avoided. If it contacts with eyes, eyes should be well-rinsed with plenty of water.
- It may cause reversible color change in mouth, on tongue and teeth. Teeth should be brushed before use in order to minimize the discoloration.
- DEVATIS SORE THROAT RELIEF SPRAY should not be swallowed and should be expectorated after each use. It is used without dilution.
- If sore throat is caused by bacterial infection or accompanied by infection, antibacterial treatment can be considered in addition to DEVATIS SORE THROAT RELIEF SPRAY use.
- As absorbed benzydamine and its metabolites are excreted in urine, possibility of systemic effect should be taken into consideration in patients with severe renal impairment.
- As absorbed benzydamine is metabolized highly in liver, possibility of systemic effect should be taken into consideration in patients with severe hepatic impairment.
- This medicinal product contains ethanol (alcohol) in small amounts – less than 100 mg per dose.

4.5 Interaction with other medicines and other forms of interaction
DEVATIS SORE THROAT RELIEF SPRAY does not have any known significant drug interaction. Chlorhexidine, one of the drug substances it contains, is incompatible with some agents:
- Chlorhexidine salts are incompatible with soap and other anionic compounds.
- Chlorhexidine salts are compatible with cationic and nonionic surface active agents; however, when they are co-administered at high concentrations, micelle may reduce chlorhexidine activity due to binding.
- Solubility of chlorhexidine salts can be increased with surfactants such as cetrimide and lissapol NX.
- It is incompatible with anionic poly-electrodes such as gum arabic, sodium alginate, sodium carboxy methyl cellulose and it is incompatible with starch and gummi tragacanthae; their effects are also reduced with

these agents.

- Chlorhexidine is also incompatible with substances such as brilliant green, chloramphenicol, copper sulphate, fluorescein sodium, formaldehyde, silver nitrate and zinc sulphate.
- As chlorhexidine interacts with Ca and Mg cations when diluted with hard water, it may precipitate as insoluble salts.
- If solutions of chlorhexidine salts combined with benzoates, bicarbonates, carbonates, borates, nitrates, phosphates and sulphates are more concentrated than 0.05%, its solubility precipitates as it will form salts with less solubility. As cetrimide enhances solubility of these salts, these precipitations do not occur when they are combined with cetrimide.
- Chlorhexidine gluconate is compatible with cetrimide and benzalkonium chloride. These synergistically enhance bactericide effect. Cetrimide prevents precipitation of chlorhexidine with hard waters.
- Except for chlorhexidine gluconate, chlorhexidine and its salts dissolve better in alcohol than water. Chlorhexidine gluconate solution may precipitate when it is added over alcohol. Ethanol in formulation renders the solution more effective against gram negative microorganisms. They can be adsorbed during filtration through cellulosic filters.

Drug interactions with benzydamine have not been reported.

4.6 Fertility, pregnancy and lactation

General recommendation
Pregnancy category is C.

Women with child-bearing potential/Contraception
DEVATIS SORE THROAT RELIEF SPRAY does not have any effect on contraception; however, as DEVATIS SORE THROAT RELIEF SPRAY contains alcohol, women with child-bearing potential should use it cautiously.

Pregnancy
DEVATIS SORE THROAT RELIEF SPRAY is contraindicated during pregnancy.
Animal studies do not indicate effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development. Potential risk to humans is unknown.

Breast-feeding
Data is not available for breastfeeding women. Therefore, it is contraindicated in breastfeeding women.

Fertility
Reproduction and fertility studies with chlorhexidine gluconate have been conducted. No evidence of impaired fertility was observed in rats, and no evidence of harm to the fetus was observed in rats and rabbits.
There is not sufficient study conducted on animals for benzydamine.

4.7 Effects on ability to drive and use machines
No effects on the ability to drive or operate machinery have been observed.

4.8 Undesirable effects
Reported undesirable effects are listed according to the following frequency. Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10000 to <1/1000), very rare (<1/10000) and unknown (cannot be estimated based on available data).

DEVATIS SORE THROAT RELIEF SPRAY is generally well-tolerated and its side effects are minor.
There is not any serious side effect and adverse effect reported at the end of clinical studies.
Mostly, local side effects are observed. Systemic side effects, generally, are not observed and not serious.

Immune system disorders:
Very rare: Allergic reaction, hypersensitivity and anaphylaxis

Central nervous system disorders:
Very common: Temporary numbness in the mouth
Common: Stinging and burning sensation in the mouth
Unknown: Dizziness, headache and drowsiness

Endocrine system diseases:
Very rare: Temporary swelling of parotid gland

Respiratory, chest disorders and mediastinal diseases:
Very rare: Laryngospasm, bronchospasm
Unknown: Pharyngeal irritation, coughing

Gastrointestinal diseases
Common: Nausea, vomiting, retching
Unknown: Dry mouth

Skin and subcutaneous tissue diseases:
Very rare: Irritation-associated skin reactions, itching accompanied by rash, urticaria, photodermatitis and oral desquamation

General disorders and administration site diseases:
Other side effects like local dryness or thirst, tingling, feeling of coolness in the mouth and altered taste and staining of teeth and other oral surfaces and increased calculus formation generally occur less. Tooth staining is harmless and can be minimized through tooth-brushing before application.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorization 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 https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose
Intoxication is not possible considering method of administration of the drug substance.
However, if DEVATIS SORE THROAT RELIEF SPRAY is accidentally swallowed, symptomatic treatment should be instituted. There is no specific antidote.

For further advice on management of overdose please contact the National Poisons Information Centre (0800 POISON or 0800 764 766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic Group: Antiseptic (Topical Pharyngeal), Topical oral anti-inflammatory
ATC code: A01AD02

Benzydamine is an anti-inflammatory analgesic agent structurally unrelated to the steroid group. Benzydamine differs from other non steroid anti-inflammatory agents in that it is a base.
At concentrations used for topical treatment, benzydamine exerts local anesthetic effect. The analgesic activity of benzydamine was more reported in models involving experimental inflammation rather than non-inflammatory pain.

The mechanism of anti-inflammatory action of benzydamine is not related to stimulation of the pituitary-adrenal axis. Like other non steroidal anti-inflammatory agents, benzydamine inhibits the biosynthesis of prostaglandins under certain conditions, but its properties in this respect have not been fully explained. The stabilizing effect on cellular membranes may be involved in the mechanism of action.

Following normal topical application of the medicine, chlorhexidine produces bactericidal effect, followed by a prolonged bacteriostatic action.

Chlorhexidine is a biguanide antiseptic that helps to reduce the development of plaque and gingivitis when usual oral hygiene measures are interrupted. It is a strong base with affinity for oral structures including hydroxyapatite of tooth enamel, pellicle of tooth surface, bacteria and salivary proteins. Chlorhexidine reduces dental plaque deposition and associated gingivitis as characterized by redness, swelling or bleeding of the gingiva. It reduces frequency of aphthous ulcer formation and increases the rate of healing following periodontal surgery.

Chlorhexidine is active against a wide range of microorganisms including gram-positive, gram-negative bacteria, yeast and some fungi and viruses. Chlorhexidine appears to delay bacterial growth by a delayed surface action. It is absorbed onto microbial cell walls and causes membrane leakage.

5.2 Pharmacokinetic properties

General characteristics

Absorption: Following topical administration of DEVATIS SORE THROAT RELIEF SPRAY, benzydamine is well-absorbed into the inflamed local mucosa where it exerts its anti-inflammatory and local anesthetic effects.

Distribution: Approximately 30% of the applied chlorhexidine gluconate is retained in the oral cavity and it is slowly released into the oral fluids for 24 hours.

Biotransformation: Absorbed benzydamine is highly metabolized in the liver.

Elimination: Absorbed benzydamine and its metabolites are excreted in the urine.

5.3 Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
The other ingredients are saccharin sodium, glycerine, polysorbate 20, ethanol, purified water, peppermint flavor, sodium hydrogen carbonate/HCl (used as pH adjusting agent, if needed).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store at or below 25°C and protect from light. Store in an upright position

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

6.6. Special precautions for disposal
No special requirements for disposal.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Pharmacy Medicine.

8. SPONSOR

DEVATIS LIMITED
45 Yarrow Street
Invercargill 9810, New Zealand
Tel: +64 3 211 0080
Fax: +64 3 211 0079
www.devatis.nz

9. DATE OF FIRST APPROVAL

Date of first authorization: 17.08.2017
Date of latest renewal:

10. DATE OF REVISION OF THE TEXT

October 2021