

Module 1.3.1.1 Professional Information
for CORYX THROAT Solution

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM**CORYX THROAT** Solution**COMPOSITION**

Each 100 mL of solution contains:

Benzocaine 266,667 mg

Chlorhexidine gluconate solution 20 % 1,0 mL

Preservative: Ethanol 96 % 11,5 % v/v

Other ingredients: Acesulfame-K, carmoisine red, cinnamon flavour, ethanol 96 %, glycerine, mint aniseed flavour, polyoxyl 40 hydrogenated castor oil, propylene glycol and purified water.

Contains sweetener (acesulfame-K) 0,05 g per 100 mL.

Sugar free.

PHARMACOLOGICAL CLASSIFICATION

A.16.3 Surface anaesthetics

PHARMACOLOGICAL ACTION

AL

Pharmacodynamics:

Benzocaine has mild local anaesthetic properties.

Chlorhexidine is a bactericidal cationic antiseptic. It acts by destroying the bacterial cell membrane and precipitating the cell cytoplasm. It has been shown that chlorhexidine binds on to the hydroxyapatite of tooth enamel, on to the pellicle of the tooth surface and on to salivary mucins. It slowly desorbs from these sites exerting a prolonged bactericidal effect for several hours.

Pharmacokinetics:

Benzocaine is readily absorbed through mucous membranes, and through damaged skin. Local anaesthetics are weak bases and at tissue pH can diffuse through connective tissue and cellular membranes to reach the nerve fibres where ionisation can occur. Benzocaine is hydrolysed by esterase in the plasma and to a lesser extent, in the liver.

Chlorhexidine is poorly absorbed from the gastrointestinal tract and intact skin.

INDICATIONS

CORYX THROAT is indicated for the temporary relief of pain and discomfort in sore throats due to colds (and accompanying tickling cough). It is also recommended for minor mouth irritations.

CONTRAINDICATIONS

CORYX THROAT is contraindicated in patients with a history of hypersensitivity to local anaesthetics or to any of the other ingredients of CORYX THROAT.

WARNINGS AND SPECIAL PRECAUTIONS

CORYX THROAT may not be used in children under the age of 2 years.

Warnings:

Do not swallow.

Special precautions:

Some patients may experience a bitter aftertaste in the mouth after rinsing the mouth with CORYX THROAT. Rinsing the mouth with water immediately after using CORYX THROAT may increase the bitterness and decreases the effect of CORYX THROAT.

CORYX THROAT may alter the taste of food in some patients. This effect may last up to 4 hours after the use of the oral rinse. In most cases this effect will become less noticeable as the patient continues to use CORYX THROAT. When the use of CORYX THROAT is stopped, taste should return to normal.

CORYX THROAT contains acesulfame-K and must not be given to patients with phenylketonuria.

INTERACTIONS

No known interaction with other medicines.

PREGNANCY AND LACTATION

The safety of CORYX THROAT in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Do not exceed the recommended dose.

Gargle:

Adults: 15 - 30 mL (3 - 6 medicine measuresful)

Children 6 to 12 years of age: 5 – 15 mL (1 – 3 medicine measuresful)

Use CORYX THROAT undiluted or diluted with a small quantity of warm water and thoroughly rinse the mouth for about one minute every 3 - 4 hours as needed. Depending on the location of the pain, the solution should be swished around the mouth and/or used as a gargle. It should not be swallowed. CORYX THROAT should generally be used undiluted, but if stinging occurs, the rinse may be diluted with a small quantity of warm water.

Spray:

Adults: Spray four (4) to eight (8) sprays directly onto the painful or inflamed area, with a maximum 32 sprays per day.

Children 6 to 12 years of age: Spray two (2) to four (4) sprays directly onto the painful or inflamed area, with a maximum of 16 sprays per day.

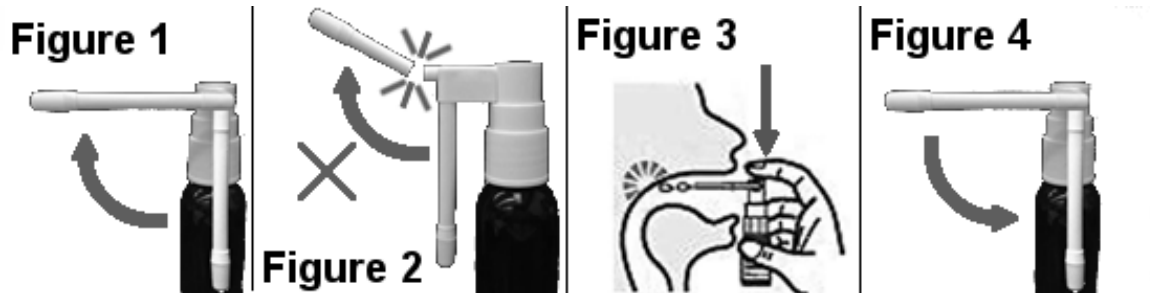
Rinse mouth and back of throat with the solution. Do not swallow the (excess) solution.

Repeat every one and a half (1½) to three (3) hours as necessary.

How to use the spray (see pictures)

- 1. Remove the transparent cap from the nozzle before use.**

2. Turn the nozzle sideways and upwards for 90 degrees in a clockwise direction (Figure 1).



3. Do not pull the nozzle upwards and to the front (Figure 2).
4. When using for the first time, depress/push the spray cap a few times until liquid is sprayed out from the nozzle.
5. Spray the correct number of sprays (see above for the Dosage) directly onto the painful or inflamed area, in the back of the throat, while avoiding spraying directly onto the teeth (Figure 3).
6. Do not breathe in while spraying as liquid may enter the bronchus or lung if sprayed while breathing in.
7. After use, rinse the tip of the nozzle under warm water, dry and turn the nozzle back to the original position for storage (Figure 4).
8. After use, replace the transparent cap to cover the nozzle.

SIDE EFFECTS

Immune system disorders:

Less frequent: Signs of allergic reactions may include nasal congestion; shortness of breath or troubled breathing; skin rash; hives or itching; or swelling of the face.

Eye disorders:

Less frequent: Irritation of the conjunctiva.

Skin and appendages disorders:

Less frequent: Local skin sensitivity reactions, prolonged use may cause discolouration of the teeth. Large swellings in the mouth or throat.

Gastro-intestinal disorders:

Less frequent: Irritation of the mucous membranes, tongue tip irritation, reversible discolouration of tongue, teeth and or composite dental restorations. Taste disturbances and a burning of the tongue. Increase in tartar (calculus) on teeth.

Body as a whole – general disorders:

Less frequent: Swollen glands on side of face or neck.

Post-marketing:**Blood and the lymphatic system disorders:**

Frequency unknown: CORYX THROAT may cause methaemoglobinaemia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

The main consequence of ingestion is mucosal irritation. Gastric lavage with demulcents is suggested for acute ingestion.

Methaemoglobinaemia has occurred in infants after absorption of benzocaine. Excitation with subsequent depression of the central nervous system. Treatment is symptomatic. If you think your child has swallowed CORYX THROAT get emergency help at once. In addition, if a child of any age drinks CORYX THROAT and has symptoms of alcohol intoxication, such as slurred speech, sleepiness, or a staggering or stumbling walk get emergency help immediately.

IDENTIFICATION

Red to pink, slightly opaque solution.

PRESENTATION

Gargle: Amber glass bottles with a white plastic screw-on cap containing 200 mL solution.

The bottle is packed into an outer carton.

Spray: Amber plastic bottles with a white plastic screw-on cap with spray nozzle containing 100 mL solution. The bottle is packed into an outer carton.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

AL

W/16.3/58

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF
REGISTRATION**

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