

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

Entop Spray, 50 mg/ 5 mg per ml, Nasal and Pharyngeal spray

Lidocaine hydrochloride/ Phenylephrine hydrochloride

Contains benzalkonium chloride solution 0,01 % w/v

Read all of this leaflet carefully because it contains important information for you

Entop spray is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Entop Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Entop 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 Entop Spray is and what it is used for
2. What you need to know before you use Entop Spray
3. How to use Entop Spray
4. Possible side effects
5. How to store Entop Spray
6. Contents of the pack and other information

1. What Entop Spray is and what it is used for

Entop Spray contains two active ingredients lidocaine (lignocaine) hydrochloride and phenylephrine

hydrochloride. The active ingredients are local anaesthetic (lidocaine) which causes numbness and a sympathomimetic medicine (phenylephrine) that reduces bleeding.

Entop Spray is used for the following:

- To numb the inside of your nose or throat before surgery or endoscopy (a procedure used to look inside the body using an endoscope)
- To help numb the nose if a foreign body (such as a small bead or any other small object becomes wedged in the nose) needs removing
- To numb the inside of your nose or throat before having a fine telescope passed into your nose or throat to view (laryngoscopy and endoscopy).

2. What you need to know before you use Entop Spray

Do not use Entop Spray:

- if you are hypersensitive (allergic) to lidocaine hydrochloride or phenylephrine hydrochloride or to any of the other ingredients of Entop Spray (listed in section 6).
- if you are hypersensitive to other local anaesthetics or sympathomimetic medicines
- if you are pregnant or breastfeeding
- if you have low blood volume in your body (hypovolaemia)
- if you have high blood pressure (hypertension)
- if you have problems with your heart such as coronary heart disease and complete heart block (problems with electrical signals in your heart).
- if you have an overactive thyroid gland (thyrotoxicosis)
- if you have the eye condition glaucoma (increased pressure in the eyeball)
- if you have problems passing urine
- for children under 12 years of age

Warnings and precautions

Take special care with Entop Spray

Tell your doctor or pharmacist before you are given Entop spray if you have or have had:

- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above
- Heart disease (i.e. heart attack or bradycardia which means a slower than normal heartbeat rate. Lidocaine, the anaesthetic medicine may make the effect of any heart rhythm regulating medicines much greater and therefore may adversely affect your heart)
- Are taking other medicines (See 'Other medicines and Entop Spray') and have a condition that affects both your heart or blood vessels, diabetes mellitus, high blood pressure, an overactive thyroid gland, low blood oxygen levels, high blood carbon dioxide levels and inherited blood disorder called porphyria
- You suffer from liver disease
- You suffer from kidney problems (kidney disease may change the blood concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of lidocaine on the heart muscle)
- You suffer from asthma and you are allergic to sulphite.
- A genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions
- You have any cut or sore area in your nose or throat
- Have epilepsy (fits)
- Have angina pectoris (disease affecting the heart blood vessels)
- Have a history of high pressure in the eye as this medicine can cause your pupils to dilate which can aggravate this condition

Children and adolescents

Entop Spray is not for children under 12 years of age.

Other medicines and Entop Spray

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not take Entop Spray with the following medicines:

- Mono Amide Oxidase Inhibitors (MAOIs; medicines used for depression) or if you have taken them within the last two weeks
- Beta-blockers e.g. propranolol (medicines used in the treatment of heart problems or high blood pressure)
- Medicines for treatment of irregular heartbeat (heart dysrhythmias)
- Diuretics (medicine used to treat high blood pressure; difficulty in passing urine and water retention)
- Antidepressant medicines (tricyclic antidepressants, e.g., amitriptyline)
- You are taking anti-ulcer medicine such as cimetidine. Cimetidine is known as an enzyme inhibiting medicine. These medicines can cause the blood level of lidocaine to rise to levels which can cause side effects
- Suxamethonium (a muscle relaxant)
- Doxapram (used to treat severe breathing difficulties)
- Oxytocin (used to induce labour);
- Ergot alkaloids (used to treat migraine)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with Entop Spray may adversely affect your heart)
- Anaesthetics such as chloroform, halothane or isoflurane

Entop spray with food and drink

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result into serious illness. Take care not to bite or burn your tongue or cheek with hot liquids whilst the numbness is still present.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult

your doctor, pharmacist or other healthcare provider for advice before using Entop Spray.

Pregnancy

You should not use Entop Spray during pregnancy.

Breastfeeding

You may use Entop Spray if you are breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent Entop Spray may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which Entop Spray affects you.

Entop Spray contains benzalkonium chloride

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. How to use Entop Spray

Priming before use

Attach Flexi Nozzle and depress 5 times until full spray is seen.

Do not share medicines prescribed for you with any other person.

Entop Spray is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of age:

5 squirts (sprays) per nostril

Each squirt (sprays) measures 100 microlitres of fluid. The dose of lidocaine in each squirt is 5 mg and the dose of phenylephrine in each squirt is 0,5 mg.

These doses are given once only. Your doctor may decide to increase or decrease this dose depending on your condition. Only your doctor should alter the recommended dosage.

What effects will I notice after taking the medication

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine.

You might also notice that the side of the nose to which the medication has been applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

If you use more Entop Spray than you should

Since a healthcare provider will administer Entop Spray, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use Entop Spray

Do not receive a double dose to make up for forgotten individual doses.

4. Possible side effects

Entop Spray can have side effects.

Not all side effects reported for Entop Spray are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Entop Spray, please consult your healthcare provider for advice.

If any of the following happens, stop taking Entop Spray and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting (dizziness).

These are all very serious side effects. If you have them, you may have had a serious reaction to Entop Spray. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- a sensation that the heart is racing, pounding, fluttering or skipping a beat, often bothersome, but hardly ever a sign of heart disease

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- bitter taste in the mouth. It only lasts for one to two minutes and then disappears

Less frequent

- involuntary shaking or movement, ranging from slight to severe and commonly affecting hands, legs, face, head or vocal cords
- nervousness, light headedness
- nausea, vomiting
- enlargement of the pupils (mydriasis)
- ringing in the ears

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, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: https://www.sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf. By reporting side effects, you can help provide more information on the safety of ENTOP SPRAY.

5. How to store ENTOP SPRAY

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 30 °C.

Do not use after the expiry date stated on the label / carton / bottle.

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 Entop Spray contains

The active substance(s) are lidocaine hydrochloride and phenylephrine hydrochloride.

Entop Spray contains 50 mg lidocaine hydrochloride and 5 mg phenylephrine hydrochloride per millilitre.

The other ingredient(s) are: benzalkonium chloride, disodium edetate, sodium metabisulfite, sodium phosphate – monobasic (pH adjustment), sodium hydroxide (pH adjustment), citric acid (pH adjustment), water purified.

What Entop Spray looks like and contents of the pack

Entop Spray is a clear solution.

Entop spray is supplied in white 50 ml HDPE bottles with screw on pump, packaged in outer carton made of cardboard.

The Flexi Nozzle for the application is available separately.

Medfour Healthcare CC

Entop Spray

Lidocaine hydrochloride 50 mg/ml

Phenylephrine hydrochloride 5 mg/ml

Approved Patient Information Leaflet

22 November 2022

The following pack size is proposed:

Bottle: 50 mL white, HDPE bottle

Pump: White screw on pump with dip tube

Holder of Certificate of Registration

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