

PACKAGE LEAFLET: INFORMATION FOR THE USER

ENZEZE 5MG/0.5MG/ACTION ANAESTHETIC SPRAY (lidocaine hydrochloride and phenylephrine hydrochloride)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This medicine will **only** be given to you by a doctor or nurse.

Please tell your doctor or nurse if you are taking any other medicines.

This product will be referred to as Enzeze throughout the leaflet.

What is in this leaflet

1. What Enzeze is and what it is used for
2. What you need to know before you are given Enzeze
3. How to use Enzeze
4. Possible side effects
5. How to store Enzeze
6. Contents of the pack and other information

1. WHAT ENZEZE IS AND WHAT IT IS USED FOR

Enzeze contains a combination of the medicines lidocaine hydrochloride and phenylephrine hydrochloride. Lidocaine hydrochloride belongs to a group of medicines called 'local anaesthetics'. Phenylephrine hydrochloride belongs to a group of medicines called 'sympathomimetics'. Lidocaine hydrochloride works by 'numbing' the area and phenylephrine hydrochloride works by causing the small blood vessels near the surface of the tissue to constrict.

Enzeze is used for the following:

- To numb the inside of your nose or throat before surgery
- 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 ARE GIVEN ENZEZE

You should not be given Enzeze if you:

- Are allergic to lidocaine hydrochloride, phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- Are allergic to other local anaesthetics of the amide type and to other sympathomimetic agents
- Are pregnant or breast-feeding
- Have low blood volume (hypovolaemia)
- High blood pressure (hypertension)
- Have problems with your heart such as coronary heart disease and complete heart block

- Have an over active thyroid gland (thyrotoxicosis)
- Have the eye condition glaucoma
- Are having difficulty passing urine.

Enzeze should not be used in children under the age of 12 years.

Warnings and precautions

Talk to your doctor or nurse before you are given this medicine if you:

- Have heart disease. Enzeze should be given with caution to patients with heart disease, especially those suffering from high blood pressure, a slow heart rate (bradycardia), conduction disturbances or severe digitalis intoxication.
- Have liver disease.
- Have kidney disease.
- Have a genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.
- Are taking other medicines (See 'Other medicines and Enzeze') and have a condition that affects both your heart or blood vessels, diabetes mellitus, high blood pressure, an over active thyroid gland, low blood oxygen levels, high blood carbon dioxide levels an inherited blood disorder called porphyria.
- Have epilepsy.
- Have angina.
- Have any damage or injury to the area that is being treated.
- Have a history of pressure in the eye as this medicine can cause your pupils to dilate which can aggravate this condition.

Other medicines and Enzeze

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take your medicine with you if you have to go to hospital.

In particular important interactions can occur with the following medicines:

- Propranolol - used to treat high blood pressure
- Cimetidine - used to treat stomach disorders
- Medicines used to treat abnormal heart rhythms - such as amiodarone and tocainide
- Phenytoin - used to treat epilepsy
- Anti-depressants - such as fluoxetine and reboxetine
- Monoamine Oxidase Inhibitors (MAOIs) or tricyclic antidepressants
- Guanethidine, reserpine and methyl dopa used to treat high blood pressure
- Digitalis used to treat heart conditions
- The antibiotic quinupristin/dalfopristin used to treat some infections
- Medicines used to treat mental conditions such as phenothiazine
- Medicines used to treat migraine such as ergotamine
- Oxytocin used in obstetrics e.g. during labour and delivery.

Some general anaesthetics and muscle relaxing medicines are used during operations. If you are going to have an anaesthetic tell your doctor, nurse or dentist you have been receiving this medicine.

Please read the SPC for Enzeze before administering to any patients.

Route of administration:

Nasal or pharyngeal.

Preparation instructions:

No special preparation instructions are required. Each 15ml bottle is accompanied by a disposable flexi nozzle.

Enzeze with food and drink

Do not eat or drink 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 in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids while your throat is still numb.

Pregnancy and breast-feeding

You should not use this medicine if you are pregnant or breast-feeding.

If you have any questions regarding the use of Enzeze during pregnancy and breast-feeding you should talk to your doctor.

Driving and using machines

Enzeze is not likely to affect you being able to drive or use any tools or machines. However, if you feel that this medicine has affected you, you should not drive or use machinery until you feel better.

Enzeze contains benzalkonium chloride

This medicine contains 0.02mg benzalkonium chloride in each 100µl actuation (or spray). Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma. Benzalkonium chloride may cause local irritation.

3. HOW TO USE ENZEZE

Enzeze will always be given to you by a doctor or nurse.

For single use only. To be discarded after first use.

Adults and children over 12 years of age:

The recommended dose is 5 sprays in each nostril or 5 sprays to the throat.

This dose is given once only. Your doctor may decide to increase or decrease this dose depending on your condition.

This medicine is not for use in children under the age of 12 years.

If you are given more Enzeze than you should

This medicine will only be given to you by a doctor or nurse who will have carefully measured the dose.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic Reactions

Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

If you notice any of the above reactions you should tell your doctor or nurse immediately.

The most common side effect is a bitter taste in the mouth. This usually lasts for one to two minutes and then disappears. Other common side effects are nausea and vomiting.

Other side effects that have been reported for Enzeze are:

- Tremor
- Palpitations
- Nervousness
- Tinnitus (ringing in the ears)
- Dizziness
- Numbness
- Disorientation
- Hypertension (high blood pressure)
- Enlargement of the pupils (mydriasis).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ENZEZE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in original container in order to protect from light. Do not refrigerate or freeze. This medicine will be stored in the pharmacy.

This medicine will be disposed of by your doctor or nurse.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Enzeze contains

The active substances are lidocaine hydrochloride and phenylephrine hydrochloride.

The other ingredients are sodium phosphate monobasic, disodium edetate, benzalkonium chloride, sodium hydroxide and citric acid.

What Enzeze looks like and contents of the pack

Enzeze is a clear colourless to very pale yellow liquid packaged in a white high density polyethylene bottle with a white screw on pump. A flexible polypropylene spray nozzle with atomiser is included in each pack for administration of the product. Each bottle contains 4.9 ml of solution.

Marketing Authorisation Holder

MMEU Limited, 2 Burns Drive, Rotherham, S65 2QH, UK

Manufacturer

Elara Pharmservices Ltd, DE74 2QD, UK.

This leaflet was last revised in November 2020.

Storage:

Do not store above 30°C. Store in original container in order to protect from light. Do not refrigerate or freeze.

An expiry date is given on the outer carton and the bottle label. Do not use after this date.

Please refer to the SPC for further information.

Enzeze 5mg/0.5mg/action anaesthetic spray

PLEASE DETACH BEFORE HANDING THE ABOVE SECTION TO THE PATIENT.

INFORMATION FOR HEALTHCARE PROFESSIONALS

Below is a summary of information to assist in the administration of Enzeze.

Product Name	Enzeze Co-phenylcaine Nasal Spray Leaflet
Dimensions	185mm x 296mm
Min Font Size	9pt
Version	3
Last Updated	18.11.2020
Colours	1. Black 2. Keyline