

Lidocaine Hydrochloride 5 % w/v and Phenylephrine Hydrochloride 0.5 % w/v Topical Solution

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.

What is in this leaflet:

1. What Lidocaine and Phenylephrine topical solution is and what it is used for
2. What you need to know before you are given Lidocaine and Phenylephrine topical solution
3. How you will be given Lidocaine and Phenylephrine topical solution
4. Possible side-effects
5. How to store Lidocaine and Phenylephrine topical solution
6. Contents of the pack and other information.

1. What Lidocaine and Phenylephrine Topical Solution is and what it is used for

The name of this product is Lidocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v topical solution. The active ingredients are local anaesthetic (lidocaine) which causes numbness and a sympathomimetic drug (phenylephrine) that reduces bleeding.

Lidocaine and phenylephrine topical solution is applied to the area inside your nose and throat to numb the area, and reduce bleeding prior to performing certain surgical procedures.

It is also used to aid in the removal of foreign bodies from the nose.

2. What you need to know before you are given Lidocaine and Phenylephrine Topical Solution

Do not use Lidocaine and Phenylephrine topical solution if:

- you are allergic to Lidocaine, local anaesthetics similar to lidocaine, Phenylephrine or any of the ingredients of this medicine (listed in section 6)
- you are pregnant or breastfeeding.
- you have a low amount of blood in your body (hypovolaemia);
- you suffer from high blood pressure;
- you suffer from a type of heart disease known as acute ischaemic heart disease;
- you have some problems with electrical signals in your heart e.g. you need a pacemaker (a device that regulates heart beats);
- you suffer from problems with your thyroid gland (thyrotoxicosis);
- you suffer from glaucoma (increased pressure in the eyeball);
- you have difficulty passing urine.
- you are taking a type of medicine known as sympathomimetics, this can include medicines used to treat asthma, colds, flu, glaucoma, heart problems, blood pressure and premature labour;
- you are taking monoamine oxidase inhibitors, (drugs used to treat depression) or have taken them within the last two weeks.

Warnings and precautions

Talk to your doctor or pharmacist before you are given Lidocaine and Phenylephrine topical solution if:

- you have any condition affecting the heart or blood vessels (cardiovascular disease);
- you suffer from diabetes;
- you suffer from high blood pressure
- you have an overactive thyroid gland;
- you suffer from low blood oxygen level or a high blood carbon dioxide level (for example you suffer from any lung disease);
- you suffer from porphyria (a hereditary disorder that affects some enzymes in the blood and liver);
- you have any cut or sore area in your nose or throat;
- you suffer from fits;
- you suffer from heart conditions which includes a slow heart rate;
- you have liver problems;
- you are suffering from severe shock (sweating, feel unwell, feeling your heartbeat, fainting);
- you suffer from angina.

Other medicines and Lidocaine and Phenylephrine topical solution: You **MUST NOT** use Lidocaine and Phenylephrine topical solution if you are taking

- MAOIs or if you have taken them within the last two weeks
- drugs for treatment of irregular heart beat (heart arrhythmias), such as lidocaine, digoxin or tocinide.

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines including:

- beta-blockers (drugs used in the treatment of heart problems or high blood pressure);
- debrisoquine, reserpine, methyl dopa and guanethide (used to treat high blood pressure);
- quinupristin/dalfopristin (used to treat bacterial infections resistant to antibiotics);
- diuretics (drugs used to treat difficulty in passing urine and water retention);
- reboxetine (used to treat depression);
- suxamethonium (a muscle relaxant);
- ergot alkaloids (used to treat migraine);
- doxapram (used to treat severe breathing difficulties);
- oxytocin (used to induce labour);
- anaesthetics such as chloroform, halothane or isoflurane;
- phenothiazines (used to treat certain mental disorders);
- drugs used to treat depression known as tricyclic antidepressants.

These include amitriptyline, clomipramine and imipramine-monoamine oxidase inhibitors (MAOIs) (drugs used to treat depression).

If you have any doubts about whether this medicine should be administered to you, discuss this more fully with your doctor or nurse.

Pregnancy, breast feeding and fertility:

You should not be given Lidocaine and Phenylephrine Topical solution when pregnant or breast-feeding.

Driving and using machines:

It is unlikely that after using Lidocaine and Phenylephrine topical solution, your ability to drive and use machines will be affected. However, if you feel unwell you must speak to your doctor before driving or operating machinery.

3. How you will be given Lidocaine and Phenylephrine topical solution

Your doctor or nurse will administer this medicine onto the area inside your nose or throat, using the pump spray dispenser supplied with the product.

Dose:

Adults, and Children over 12 years: Up to a maximum of 8 sprays in total.

Children below 12 years of age: Not recommended.

4. Possible side-effects

Like all medicines Lidocaine and Phenylephrine topical solution can cause side effects, although not everybody gets them.

Serious Side effects

The anaesthetic effect induced by lidocaine may cause numbness of the tongue and mouth and may interfere with swallowing. Do not eat or drink until the effect has worn off. If used on damaged or inflamed skin Lidocaine and Phenylephrine topical solution may cause the following effects: Breathing difficulties, fits, coma, heart attack, chest pain, bradycardia (slow heart rate), cardiac arrhythmias (irregular heart beat) and low blood pressure (with dizziness, fainting and flushing) or high blood pressure. These are all very serious side effects and are very rare.

If any of the above happens, tell your doctor immediately or go to the casualty department at your nearest hospital as you may need urgent medical attention.

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

Difficulty in passing urine (particularly if you have problems with your prostate), blurred vision, dizziness, drowsiness, irritability, extremely high temperature, muscle twitching and shaking.

You may need medical attention.

These serious side effects are rare.

Other side effects

Tell your doctor if you notice any of the following:

Excessive saliva, headache, reduced appetite, sweating and weakness, difficulty in sleeping, feeling sick or being sick, anxiety, confusion, excitement, fear, nervousness, restlessness, fits and tinnitus. These are all mild side effects of Lidocaine and Phenylephrine topical solution.

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

5. How to store Lidocaine and Phenylephrine Topical Solution

You should not be given this medicine if the expiry date on the label has passed or if it shows signs of deterioration. The doctor or nurse will check that the expiry date on the label has not passed and that the medicine does not show signs of deterioration.

Do not store this medicine above 25°C.

Keep this medicine out of the sight and reach of children. Keep in the original container.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lidocaine and Phenylephrine Topical Solution contains:

The **active ingredients** in Lidocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v topical solution are Lidocaine Hydrochloride and Phenylephrine Hydrochloride. Each bottle contains 2.5ml of topical solution containing 50mg/ml of lidocaine hydrochloride and 5mg/ml of phenylephrine hydrochloride in Water for Injections, with sodium hydroxide and hydrochloric acid to adjust the pH.

What Lidocaine and Phenylephrine Topical Solution looks like and contents of the pack:

Lidocaine and Phenylephrine Topical Solution is licensed to be available in one bottle containing 2.5ml of solution, in a single box. Each 2.5ml of solution contains 125mg of Lidocaine Hydrochloride and 12.5mg of Phenylephrine Hydrochloride respectively.

Marketing Authorisation Holder:

Aurum Pharmaceuticals Ltd, Bampton Road, Romford, RM3 8UG, United Kingdom.

Manufacturers:

University Hospitals of Derby and Burton NHS Foundation Trust

Queen's Hospital Burton, Pharmacy Manufacturing Unit, Belvedere Road, Burton-on-Trent, DE13 0RB, United Kingdom

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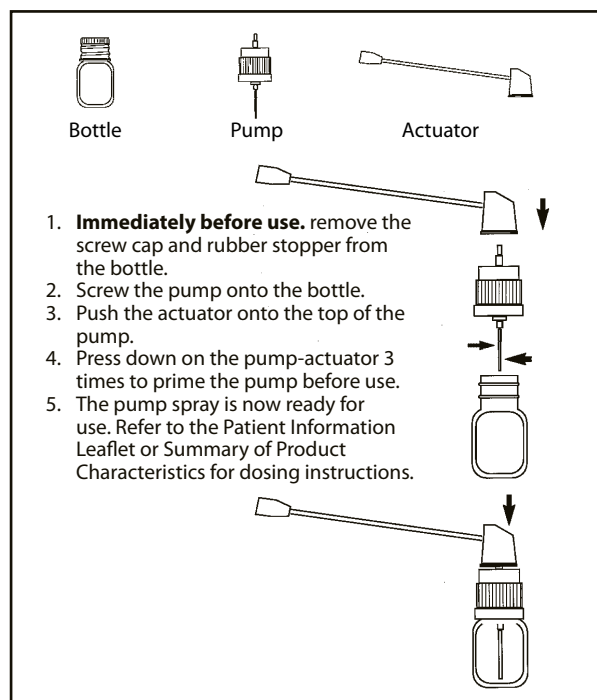
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User Guide



Instructions For Assembly Of Pump + Actuator To Bottle.

Priming the Pump.

While holding the bottle upright, the pump should be activated three times before use to prime it.

Other Information.

The pump dispenser will deliver a dose volume of 130µl in each spray. Thus, each spray is equivalent to 6.5mg of Lidocaine Hydrochloride and 0.65mg of Phenylephrine Hydrochloride. Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip.

This product is sterile until opened, and contains no preservative.

Use once for one patient only and discard the bottle and any remaining topical solution in an appropriate manner.

Do not use if packaging is damaged.

Keep out of the sight and reach of children.

This product also contains Water for Injections, with Sodium Hydroxide and /or Hydrochloric Acid to adjust pH.

MA Number/Holder

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For further information contact:

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