

## **Package leaflet: Information for the user**

### **Prilocaine hydrochloride 1% Solution for Injection** prilocaine hydrochloride

**Read all of this leaflet carefully before you start using 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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

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

## **1. What Prilocaine solution for injection is and what it is used for**

Prilocaine solution for injection contains a medicine called prilocaine hydrochloride. This belongs to a group of medicines called local anaesthetics.

Prilocaine is used in adults and children above 6 months in age to numb (anaesthetise) parts of the body. It stops pain happening during medical procedures and surgery (operations).

## **2. What you need to know before you use Prilocaine solution for injection**

#### **Do not use Prilocaine solution for injection:**

- if you are allergic to prilocaine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to any other local anaesthetics of the same class (such as lidocaine or bupivacaine).
- if you are anaemic (a blood problem which means you have too few red blood cells).
- if you have a problem with blood pigment levels called 'methaemoglobinaemia'.

You must not be given Prilocaine solution for injection if any of the above apply to you. If you are not sure, talk to your doctor before you are given Prilocaine solution for injection.

#### **Warnings and precautions**

Talk to your doctor or nurse before using Prilocaine solution for injection if:

- you have high blood pressure or heart problems.
- you have liver or kidney problems.
- you have difficulty breathing.
- you have epilepsy.
- you have an infection or inflammation at the site where the injection is to be given.
- you have ever been told that you have a rare disease of the blood pigment called 'porphyria' or anyone in your family has it.

If you are not sure if any of the above apply to you, talk to your doctor before having Prilocaine solution for injection.

#### **Other medicines and Prilocaine solution for injection**

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because prilocaine can affect the way some medicines work and some medicines can have an effect on prilocaine.

In particular, tell your doctor if you are taking any of the following medicines:

- Other local anaesthetics.
- Medicines called sulphonamides, such as co-trimoxazole (used to treat infections caused by bacteria).
- Anti-malarial medicines (used to prevent or treat malaria).
- Nitrate medicines (used to treat heart problems).
- Medicines to treat an uneven heart beat (arrhythmia), such as amiodarone.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine.

### **Driving and using machines**

Prilocaine may make you feel sleepy and affect the speed of your reactions. After you have been given Prilocaine solution for injection, you should not drive or use tools or machines until the next day.

### **Prilocaine solution for injection contains sodium**

- Prilocaine solution for injection contains 2.36 mg of sodium per millilitre (ml), equivalent to 118 mg per 50 ml ampoule. Your doctor will take this into account if you are on a sodium controlled diet.

### **Prilocaine solution for injection contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)**

Prilocaine solution for injection contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). These may cause allergic reactions (possibly delayed) such as a skin rash, and exceptionally bronchospasm (breathlessness). This may happen a while after you have been given the medicine.

## **3. How to use Prilocaine solution for injection**

Always use this medicine exactly as your doctor or nurse has told you. Check with your doctor or nurse if you are not sure. Prilocaine will be given to you by a doctor. It will be given to you as an injection. The dose that your doctor gives you will depend on the type of pain relief that you need. It will also depend on your body size, age, and physical condition and the part of your body that the medicine is being injected into. You will be given the smallest dose possible to produce the required effect.

Prilocaine will usually be given near the part of the body to be operated on. It stops the nerves from being able to pass pain messages to the brain. It will stop you feeling pain. It will start to work a few minutes after being injected and will slowly wear off when the medical procedure is over.

### **Use in children and adolescents**

Prilocaine solution for injection is not recommended for use in children under 6 months old.

### **If you use more Prilocaine solution for injection than you should**

Serious side effects from getting too much prilocaine need special treatment and the doctor treating you is trained to deal with these situations. The first signs of being given too much prilocaine are usually as follows:

- Feeling dizzy or light-headed.
- Numbness of the lips and around the mouth.
- Numbness of the tongue.
- Hearing problems.
- Problems with your sight (vision).

To reduce the risk of serious side effects, your doctor will stop giving you prilocaine as soon as these signs appear. This means that if any of these happen to you, or you think you have received too much prilocaine, **tell your doctor immediately.**

More serious side effects from being given too much prilocaine include problems with your speech, twitching of your muscles, tremors, trembling, fits (seizures), and loss of consciousness, low blood pressure, erratic heart beat, slowing or stopping of your heart.

#### **4. Possible side effects**

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

If you have any of these side effects, **stop** taking the medicine and/or seek urgent medical advice **immediately:**

- Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
- Severe or sudden swelling of your hands, feet and ankles.
- Difficulty breathing.
- Severe itching of the skin (with raised lumps).

#### **Other possible side effects:**

##### **Very common: may affect more than 1 in 10 people**

- Low blood pressure. This might make you feel dizzy or light-headed.
- Feeling sick (nausea).

##### **Common: may affect up to 1 in 10 people**

- Being sick (vomiting).
- Feeling dizzy.
- Pins and needles.
- Slow heart beat.
- High blood pressure.

##### **Uncommon: may affect up to 1 in 100 people**

- Blurred vision.
- Ringing in the ears (tinnitus) or being sensitive to sound.
- Numbness of the lips and around the mouth.
- Numbness of the tongue.
- Difficulty in speaking.
- Loss of consciousness.
- Shakiness.
- Fits (convulsions).

##### **Rare: may affect up to 1 in 1,000 people**

- Uneven heart beat (arrhythmias).
- Heart attack.
- Nerve damage that may cause changes in sensation or muscle weakness (neuropathy). This may include peripheral nerve damage.
- Methaemoglobinaemia (a problem with blood pigment levels). If this happens, the skin becomes bluish-grey due to a lack of oxygen (this is more likely in infants).

##### **Not known: frequency cannot be estimated from the available data**

- Double vision.
- Shallow breathing.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

### **Reporting of side effects**

If you get any side effects, talk to your doctor 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.

Website: [www.mhra.gov.uk/yellowcard](http://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 Prilocaine solution for injection**

- 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 container after EXP. The expiry date refers to the last day of that month.
- Store below 25°C.
- Your doctor or the hospital will normally store Prilocaine solution for injection and they are responsible for the quality of the product when it has been opened if it is not used immediately. They are also responsible for disposing of any unused Prilocaine solution for injection correctly.

## **6. Contents of the pack and other information**

### **What Prilocaine solution for injection contains**

The active substance is prilocaine hydrochloride. Each millilitre (ml) of solution contains 10 mg of prilocaine hydrochloride (500 mg per 50 ml vial).

The other ingredients are sodium chloride, hydrochloric acid and/or sodium hydroxide, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and water for injections.

### **What Prilocaine solution for injection looks like and contents of the pack**

Prilocaine solution for injection is a solution for injection. It comes in glass multi-dose vials of 20 ml or 50 ml.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland  
Tel: +44 (0)1 748 828 391

Manufacturer: AstraZeneca UK Ltd, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.  
Recipharm Monts, Usine de Monts, 18, rue de Montbazon, F-37260, Monts, France

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

<b>Product name</b>	<b>Reference number</b>
Prilocaine hydrochloride 1% Solution for Injection	39699/0073

This is a service provided by the Royal National Institute of Blind People.

**This leaflet was last revised in April 2022.**