

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Lidocaine/Prilocaine 5% cutaneous patch

#### Lidocaine/Prilocaine

Read all of this leaflet carefully before you or your child start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor, pharmacist or nurse if you need more information or advice.
- If you get any of the side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

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

#### 1. What Lidocaine/Prilocaine 5% cutaneous patch is and what it is used for

Lidocaine/Prilocaine 5% cutaneous patch contains the medicines lidocaine and prilocaine. These belong to a group of medicines called local anaesthetics.

Lidocaine/Prilocaine 5% cutaneous patch works by numbing the surface of the skin for a short time. It is put on the skin before certain medical procedures. This helps to stop pain on the skin; however you may still have the feelings of pressure and touch.

#### Adults, Adolescents and Children

It can be used to numb the skin before:

- Having a needle put in (for example, if you are having an injection or a blood test).
- Minor skin operations.

#### 2. What you need to know before you use Lidocaine/Prilocaine 5% cutaneous patch

##### Do not use Lidocaine/Prilocaine 5% cutaneous patch:

- if you are allergic to lidocaine or prilocaine, other similar local anaesthetics or any of the other ingredients of this medicine (listed in section 6).
- if you have congenital methaemoglobinaemia (a hereditary haemoglobin abnormality)
- if you have porphyria (a genetic hereditary disorder affecting the production of haemoglobin)
- if your child is 0-3 months of age and has a known or suspected rare inherited illness that affects the blood called 'glucose-6-phosphate dehydrogenase (G6PD) deficiency'.

#### Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using Lidocaine/Prilocaine 5% cutaneous patch:

- if you or your child have a rare inherited illness that affects the blood called ‘glucose-6-phosphate dehydrogenase (G6PD) deficiency’.
- if you or your child have a problem with blood pigment levels called ‘methaemoglobinaemia’.
- if you or your child have an itchy skin condition called ‘atopic dermatitis’, a shorter application time may be sufficient. Application times of longer than 30 minutes may result in an increased incidence of local skin reaction (see also section 4 “Possible side effects”).
- if you take particular products for heart rhythm disorders (class III antiarrhythmics, such as amiodarone). In that case the doctor will monitor your heart function.

Do not use Lidocaine/Prilocaine 5% cutaneous patch on areas with skin rash, cuts, grazes or other open wounds, with the exception of a leg ulcer. If any of these problems are present, check with your doctor, pharmacist or nurse before using the patch.

Avoid putting Lidocaine/Prilocaine 5% cutaneous patch near the eyes, as it may cause irritation. If you accidentally get the patch in your eye, you should immediately rinse your eye well with lukewarm water or salt (sodium chloride) solution. Be careful to avoid getting anything in your eye until feeling returns.

When you use Lidocaine/Prilocaine 5% cutaneous patch before being vaccinated with live vaccines (e.g. tuberculosis vaccine), you should return to your doctor or nurse after the time period requested to follow-up the vaccination result.

The effectiveness of Lidocaine/Prilocaine 5% cutaneous patch when drawing blood from the heel could not be confirmed in clinical studies.

### **Children and adolescents**

In infants/newborn infants younger than 3 months a transient, clinically not relevant increase in blood pigment levels “methaemoglobinaemia” is commonly observed up to 12 hours after Lidocaine/Prilocaine 5% cutaneous patch is put on.

Lidocaine/Prilocaine 5% cutaneous patch should not be used in children younger than 12 months of age who are being treated at the same time with other medicines that affect blood pigment levels “methaemoglobinaemia” (e.g. sulphonamides, see also Section 2 Other medicines and Lidocaine/Prilocaine 5% cutaneous patch).

Lidocaine/Prilocaine 5% cutaneous patch should not be used in preterm newborn infants. If used in children, special monitoring is recommended to verify that the patch remains in place and to prevent possible risk of swallowing or accidental contact with the eyes following touching of the patch by the child.

### **Other medicines and Lidocaine/Prilocaine 5% cutaneous patch**

Tell your doctor or pharmacist if you are using / taking, have recently used / taken or might use / take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Lidocaine/Prilocaine 5% cutaneous patch can affect the way some medicines work and some medicines can have an effect on Lidocaine/Prilocaine 5% cutaneous patch.

In particular, tell your doctor or pharmacist if you or your child, in particular infants 0 to 3 months of age, have recently used or been given any of the following medicines:

- Medicines used to treat infections, called ‘sulphonamides’ and nitrofurantoin.
- Medicines used to treat epilepsy, called phenytoin and phenobarbital.

- Other local anaesthetics.
- Medicines to treat an uneven heartbeat, such as amiodarone.
- Cimetidine or beta-blockers, which may cause an increase in the blood levels of lidocaine. This interaction is of no clinical relevance in short-term treatment with Lidocaine/Prilocaine 5% cutaneous patch in recommended doses.

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- **dapsone**
- **metoclopramide**
- **flutamide**
- **sodium nitroprusside**

### **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 pharmacist for advice before taking this medicine.

It is preferable not to use this medicine in pregnancy.

The active substances in Lidocaine/Prilocaine 5% cutaneous patch are passed into breast milk. However, the amount is so small that there is generally no risk to the child. Lidocaine/Prilocaine 5% cutaneous patch can be used during breast-feeding if clinically needed.

Animal studies have shown no impairment of male or female fertility.

### **Athletes**

Athletes are informed that this medicinal product contains an active substance which can produce a positive reaction in anti-doping tests.

### **Driving and using machines**

Lidocaine/Prilocaine 5% cutaneous patch has no or negligible influence on the ability to drive and use machines when used at the recommended doses.

**Lidocaine/Prilocaine 5% cutaneous patch contains castor oil**  
Lidocaine/Prilocaine 5% cutaneous patch contains castor oil which may cause skin reactions, in particular in children under 3 years of age.

## **3. How to use Lidocaine/Prilocaine 5% cutaneous patch**

Always use Lidocaine/Prilocaine 5% cutaneous patch exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

### **Using Lidocaine/Prilocaine 5% cutaneous patch**

Where to put the patch, how much to use and how long to leave it on will depend on what it is used for.

Apply at least one hour prior to a procedure.

### **Adults and Adolescents**

One or two patches to be applied at least 60 minutes before having the procedure. However do not put the patch on for more than 5 hours before.

## **Children**

### *Newborn infants and infants 0-2 months:*

One patch to be applied for no longer than 1 hour. No more than one patch to be used in any 24 hour period.

### *Infants aged 3 – 11 months:*

Up to 2 patches to be applied for no longer than 1 hour.

### *Children aged 1 – 5 years:*

Up to 10 patches to be applied for 1 to 5 hours.

### *Children aged 6 – 11 years:*

Up to 20 patches to be applied for 1 to 5 hours.

A maximum of 2 doses at least 12 hours apart may be given to children over 3 months of age in any 24 hour period.

Lidocaine/Prilocaine 5% cutaneous patch can also be used on children with a skin condition called “atopic dermatitis” but the application time is then 30 minutes, no longer.

When you apply the patch, it is very important to exactly follow the instructions below:

- Make sure that the area of skin to be anaesthetised is clean and dry.
- To open the patch, take hold of the aluminium flap at the corner of the patch designed for this purpose.
- Do not touch the white disc on the patch which contains the anaesthetics.
- Discard the aluminium protective backing.
- Apply patch so that the white disc covers the area to be anaesthetised. Do not press on the centre of the patch as this prevents leakage under the adhesive.
- Press firmly around the edges of the patch to ensure good adhesion.
- Mark the time of application directly on the patch.

The patch should remain in place during the time recommended by your doctor, pharmacist or nurse, that is, at least 1 hour in adults and children over 3 months of age.

In infants 0 to 3 months of age, the maximum duration of application is 1 hour.

Your doctor or nurse will remove the patch prior to the procedure.

### **If you use more Lidocaine/Prilocaine 5% cutaneous patch than you should:**

If you use more Lidocaine/Prilocaine 5% cutaneous patch than is described in this leaflet or more than your doctor, pharmacist or nurse has told you to, talk to one of them straight away, even if you do not feel any symptoms.

Symptoms of using too much Lidocaine/Prilocaine 5% cutaneous patch are listed below. These symptoms are unlikely to happen if Lidocaine/Prilocaine 5% cutaneous patch is used as recommended.

- Feeling light-headed or dizzy.
- Tingling of the skin around the mouth and numbness of the tongue.

- Abnormal taste.
- Blurred vision.
- Ringing in the ears.
- There is also a risk of 'acute methaemoglobinaemia' (a problem with blood pigment levels). This is more likely when certain medicines have been taken at the same time. If this happens, the skin becomes bluish-grey due to a lack of oxygen.

In serious cases of overdose, symptoms may include fits, low blood pressure, slowed breathing, stopped breathing and altered heartbeat. These effects may be life-threatening.

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

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

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

If you experience any of the following effects while you are using Lidocaine/Prilocaine 5% cutaneous patch, stop using it and check with your doctor or pharmacist as soon as possible:

- Allergic reactions, which in rare cases may develop into anaphylactic shock (skin rash, swelling, fever, respiratory difficulties and fainting) during treatment.
- Methaemoglobinaemia (blood disorder), which in rare cases may develop during treatment of the skin, and may cause signs and symptoms of hypoxaemia (abnormally low level of oxygen in the blood). Methaemoglobinaemia is more frequently observed, often in connection with overdose, in newborn infants and infants aged 0 to 12 months.
- A mild reaction (paleness or redness of the skin, slight puffiness, initial burning or itching) may occur on the area on which Lidocaine/Prilocaine 5% cutaneous patch is used. These are normal reactions to the patch and the anaesthetics and will disappear in a short while without any measures being needed.

If you experience any troublesome or unusual effects while you are using Lidocaine/Prilocaine 5% cutaneous patch, stop using it and check with your doctor or pharmacist as soon as possible.

**Uncommon** (may affect up to 1 in 100 people)

- An initially mild sensation of burning, itching or warmth at the treated area during treatment of the skin).

**Rare** (may affect up to 1 in 1,000 people)

- Small dot-shaped bleeding on the treated area (particularly on children with eczema after longer application times) during treatment of the skin.
- Irritation of the eyes if Lidocaine/Prilocaine 5% cutaneous patch accidentally comes into contact with them during treatment of the skin.

#### **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 Yellow Card Scheme: [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 Lidocaine/Prilocaine 5% cutaneous patch**

Keep out of the sight and reach of children.

Do not use Lidocaine/Prilocaine 5% cutaneous patch after the expiry date stated on the outer packaging.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. This will help to protect the environment.

## 6. Contents of the pack and other information

### What Lidocaine/Prilocaine 5% cutaneous patch contains

#### The active substances are:

1 g of emulsion for a 10 cm<sup>2</sup> medicated patch contains

Lidocaine.....	0.0250 g
Prilocaine .....	0.0250 g

#### The other ingredients are:

Laminated backing foil (aluminium foil with plastic film), adsorbent disc (cellulose), adhesive foam tape (polyethylene coated ring with acrylate adhesive), macrogolglycerol hydroxystearate (hydrogenated polyethylene castor oil), carbomer, sodium hydroxide and purified water.

### What Lidocaine/Prilocaine 5% cutaneous patch looks like and contents of the pack

This medicine is a cutaneous patch consisting of an absorbent disc of approximately 10 cm<sup>2</sup> impregnated with 1 gram of an emulsion containing a mixture (1:1) of the two anesthetics lidocaine (2.5%) and prilocaine (2.5%), surrounded by an adhesive foam ring, with the entire unit adherent to a laminated backing foil acting as an occlusive dressing.

A pack contains 1 or 20 medicated patches.

### Marketing Authorisation Holder

Morningside Healthcare Ltd Unit C, Harcourt Way, Leicester, LE19 1WP, UK

### Manufacturer

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