

Package leaflet: Information for the user

<[To be completed nationally]>

Lidocaine

<[P, Pharmacy variant introduction]>

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 has told you.

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

<[POM, Prescription only variant introduction]>

Read all of this leaflet carefully before you or your child 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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others, it may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What <PRODUCT NAME> is and what it is used for

This medicine is called:

<[To be completed nationally]>

<PRODUCT NAME> is a type of medicine called a local anaesthetic, used to numb an area of the body.

<PRODUCT NAME> temporarily numbs the surface of the skin, providing pain relief when a needle is inserted into a vein (venipuncture or venous cannulation) for medical purposes, such as extracting blood for laboratory tests, for adults and children aged one month and older.

It may also be used to numb the skin prior to administration of painful topical treatments on larger surface areas of intact skin for adults only.

2. What you need to know before you use <PRODUCT NAME>

Do not use <PRODUCT NAME>:

Talk to your doctor or pharmacist-and do not use <PRODUCT NAME> if:

- You are allergic (hypersensitive) to lidocaine or to any of the other ingredients.
- You are allergic to any similar local anaesthetics.
- You are allergic to soya or peanuts (contains hydrogenated soy lecithin).

Warnings and precautions

Talk to your doctor or pharmacist before ~~use~~ using <PRODUCT NAME> if:

- You are acutely ill, debilitated or elderly (you will be more sensitive to lidocaine).
- You have a history of being sensitive to the ingredients of any medicines, particularly other local anaesthetics.
- You have a severe liver (hepatic) disease.

Other medicines and <PRODUCT NAME>

Tell your doctor or pharmacist if you are taking, have recently used or might use any other medicines, but specifically:

- <PRODUCT NAME>, lidocaine or any other local anaesthetic.
- Any medicine used to prevent or treat an irregular heart beat, such as tocainide, mexiletine or amiodarone.
- The beta blocker propranolol, for the treatment of hypertension.
- Cimetidine, for the treatment of heartburn or stomach ulcers.
- If you are about to receive a vaccination with live vaccine (e.g. tuberculosis vaccine). Vaccines should not be administered in areas where <PRODUCT NAME> has been applied as the effect of the vaccine may be affected.

Pregnancy and, 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.

Driving and using machines

<PRODUCT NAME> has no known effect on the ability to drive or operate machinery.

<PRODUCT NAME> contains propylene glycol: May cause skin irritation.

<PRODUCT NAME> contains hydrogenated soy lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

3. How to use <PRODUCT NAME>

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Using <PRODUCT NAME>:

- How you use <PRODUCT NAME> changes, depending upon why you are using the product. Make sure you choose and follow the correct dosage section overleaf.
- Your doctor or nurse will tell you where you should apply the cream. If the cream is to be used over large areas, a doctor or nurse will apply it for you.

Precautions when using <PRODUCT NAME>:

- For external use only.
- Do not apply to raw or blistered skin, where there is a skin rash or eczema, or where there are cuts, grazes or wounds.
- Do not apply in the ear, inside the nose, in the mouth, to the anus (back passage), or genital mucosa.
- Avoid getting <PRODUCT NAME> in your eyes, as it may cause severe irritation. If you accidentally get any in your eye, immediately rinse it well with lukewarm water or sodium chloride (salt) solution and protect it until sensation returns.
- Applying <PRODUCT NAME> to the skin may result in temporary blanching followed by temporary redness of the site of application.
- Application to larger areas or for longer times than recommended could cause serious adverse effects due to the absorption of lidocaine.
- **<PRODUCT NAME> blocks all sensations in the treated area. Avoid scratching, rubbing and exposure to extreme hot and cold until the anaesthetic effect has worn off.**

The recommended dose to provide pain relief when inserting a needle into a vein is:

1g of cream is approximately equal to a 5cm length of cream squeezed from the 5g tube or 3.5cm squeezed from the 30g tube.

Adults, including the elderly, and children over 1 year of age:

1g to 2.5g of cream, to cover an area of skin 2.5cm x 2.5cm (1" x 1") where the needle will be inserted. Do not leave on the skin for longer than 5 hours.

Infants over 3 months but below 1 year of age:

No more than 1g of cream should be applied. Do not leave on the skin for longer than 4 hours.

Infants over 1 month but below 3 months of age:

No more than 1g of cream should be applied. Do not leave on the skin for longer than 1 hour.

Do not use on infants below one month old.

1. Apply <PRODUCT NAME> at least 30 minutes before the medical procedure starts.
2. Using the quantity stated above, apply the cream in a uniform thick layer to the skin.
3. If the doctor or nurse tells you to do so, cover the cream with a dressing to prevent it being accidentally rubbed off the skin.
4. After approximately 30 minutes remove the dressing. Immediately remove the cream with a gauze swab.
5. Inserting a needle into the vein should be performed shortly after removing the cream.

The recommended dose to provide anaesthesia prior to administration of painful topical treatments on larger surface areas of intact skin is:

1g of cream is approximately equal to a 5cm length of cream squeezed from the 5g tube or 3.5cm squeezed from the 30g tube.

Adults and the elderly aged 18 years and over:

Use 1.5g to 2g on each 10cm² area of skin, to cover a maximum total area of 300cm² (200cm² is approximately equal to a face, 300cm² to an arm). Do not exceed the recommended dose.

1. Apply <PRODUCT NAME> approximately 30 to 60 minutes before the procedure starts.
2. Using the quantities stated above, apply the cream in a uniform thin layer to the skin.
3. Ensure the cream is not accidentally rubbed off the skin.
4. After approximately 30 to 60 minutes, remove the cream with a gauze swab.
5. The procedure should begin shortly after removal of the cream.

The cream should not be reapplied for at least 12 hours after it has been removed.

Do not use on patients below 18 years of age.

If you use more <PRODUCT NAME> than you should

Overdose is unlikely, but talk to your doctor or nurse straight away, even if you do not feel any symptoms. An overdose may include using more than the recommended amount, applying the cream to large areas or using the cream for longer than recommended.

The following overdose symptoms may be experienced: blurred vision, dizziness or drowsiness, difficulty breathing, trembling, chest pain or an irregular heartbeat.

4. Possible side effects

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

If you experience any side effect listed below, immediately remove the cream, discontinue use and talk to your doctor or pharmacist.

An allergic reaction is rare; may affect up to 1 in 1000 people. Symptoms may include a rash, swelling, very low blood pressure or anaphylactic shock.

Skin irritation, redness, itching-or rash at the site of application are common side effects which may affect up to 1 in 10 people.

You may experience eye irritation if the cream is accidentally applied to or around the eye. It is not known how many people are affected as the frequency cannot be estimated from the available data. Refer to 'Precautions when using <PRODUCT NAME>' in Section 3 for what to do immediately after accidental eye exposure.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any side effect that becomes more serious or persists, that clears up but occurs again within a few days or any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

< RMS: UK: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard >

<To be completed nationally>

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

5. How to store <PRODUCT NAME>

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

Do not freeze.

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

After opening the tube, the shelf life is 6 months.

Do not throw away any medicines via wastewater or household waste. 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 <PRODUCT NAME> contains

- The active substance is lidocaine. 1g of cream contains 40mg of lidocaine.
- The other ingredients are benzyl alcohol, carbomers, cholesterol, hydrogenated soy lecithin, polysorbate 80, propylene glycol, trolamine, all-*rac*- α -tocopheryl acetate and purified water.

What <PRODUCT NAME> looks like and contents of the pack

<PRODUCT NAME> is a white to off-white yellowish cream presented in either:

- an aluminium tube with an epoxyphenolic internal lacquer fitted with a polypropylene screw cap or

- an aluminium tube with a polyamide-imide internal lacquer fitted with a high density polyethylene screw cap.

Pack sizes:

- Carton with 1 x 5g or 5 x 5g tubes
- Carton with 1 x 5g or 5 x 5g tubes including 2 or 10 occlusive dressings.
- Carton with 1 x 30g tube

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

<[To be completed nationally]>

Manufacturer:

<[To be completed nationally]>

This medicinal product is authorised in the Member States of the EEA under the following names:

<[To be completed nationally]>

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