PACKAGE LEAFLET

Package leaflet: Information for the user

Dolocopin 40mg/g Cream
lidocaine

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 Dolocopin is and what it is used for

This medicine is called: Dolocopin

Dolocopin is a type of medicine called a local anaesthetic, used to numb an area of the body.

Dolocopin 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 Dolocopin

Do not use Dolocopin:
Talk to your doctor or pharmacist and do not use Dolocopin 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 using Dolocopin 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 Dolocopin
Tell your doctor or pharmacist if you are taking, have recently used or might use any other medicines, but specifically:
- Dolocopin, lidocaine or any other local anaesthetic.
- Any medicine used to prevent or treat an irregular heart beat, such as tocainide, mexiletime or amiodarone.
- The beta blocker propranolol, for the treatment of hypertension.
- Cimetidine, for the treatment of heatburn or stomach ulcers.

- If you are about to receive a vaccination with live vaccine (e.g. tuberculosis vaccine). Live vaccines should not be administered in areas where Dolocopin 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
Dolocopin has no known effect on the ability to drive or operate machinery.

Dolocopin contains 75mg propylene glycol in each 1g: Propylene glycol may cause skin irritation.

Doclocopin contains 15mg benzyl alcohol in each 1g. Benzyl alcohol may cause allergic reactions or mild local irritation.

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

3. How to use Dolocopin

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 Dolocopin:
- How you use Dolocopin 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 Dolocopin:
- 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 Dolocopin 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 Dolocopin 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.
- **Dolocopin 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 Dolocopin 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 10cm^2 area of skin, to cover a maximum total area of 300cm^2 (200cm^2 is approximately equal to a face, 300cm^2 to an arm). Do not exceed the recommended dose.

1. Apply Dolocopin 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 Dolocopin 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 Dolocopin' 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 effects 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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dolocopin

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

This medicinal product does not require any special storage conditions. 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. Content of the pack and other information

What Dolocopin 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 Dolocopin looks like and contents of the pack

Dolocopin 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:
Ferndale Laboratories Ltd, Lee View House, South Terrace, Cork, T12 T0CT, Ireland.
Manufacturer:
Laboratório Medinfar S.A., Rua Henrique de Paiva Couceiro, Nº 27, Venda Nova 2700-451 Amadora – PORTUGAL.

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

Germay: LidoGalen
Ireland: Dolocopin
Italy: Asensil
Sweden: Maxilene

This leaflet was last revised in June 2023