Package leaflet: Information for the user

Lidocaine Grünenthal 700 mg medicated plaster
Lidocaine

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 pharmacist.
- 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you use Lidocaine Grünenthal medicated plaster
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1. What Lidocaine Grünenthal medicated plaster is and what it is used for

Lidocaine Grünenthal medicated plaster contains lidocaine, a local analgesic, which works by reducing the pain in your skin.

You have been given Lidocaine Grünenthal medicated plaster to treat a painful skin condition called post-herpetic neuralgia. This is generally characterised by localised symptoms such as burning, shooting or stabbing pain.

2. What you need to know before you use Lidocaine Grünenthal medicated plaster

Do not use Lidocaine Grünenthal medicated plaster
- if you are allergic to lidocaine or any of the other ingredients of this medicine (listed in section 6)
- if you have had an allergic reaction to other products which are similar to lidocaine, such as bupivacaine, etidocaine, mepivacaine or prilocaine
- on injured skin or open wounds

Warnings and precautions
Talk to your doctor or pharmacist before using Lidocaine Grünenthal medicated plaster.

If you have severe liver disease, or severe heart problems, or severe kidney problems, you should talk to your doctor before using Lidocaine Grünenthal medicated plaster.

Lidocaine Grünenthal medicated plaster should only be used on the areas of skin after the shingles has healed. It should not be used on, or near the eyes or mouth.

Lidocaine is broken down in your liver to several compounds. One of these compounds is 2,6 xylidine which has been shown to cause tumours in rats when given lifelong in very high doses. The significance of these findings in humans is not known.

Children and adolescents
Lidocaine Grünenthal medicated plaster has not been studied in patients under 18 years of age. Therefore it is not recommended for use in this patient population.

Other medicines and Lidocaine Grünenthal medicated plaster
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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.

Lidocaine Grünenthal medicated plaster should not be used in pregnancy unless clearly necessary.

There are no studies of the plaster in breast-feeding women. When using Lidocaine Grünenthal medicated plaster, only very small amounts of the active substance lidocaine may be present in the blood stream. An effect on breast-fed infants is unlikely.

Driving and using machines
An effect of Lidocaine Grünenthal medicated plaster on the ability to drive and use machines is unlikely. Therefore you may drive or operate machinery whilst using Lidocaine Grünenthal medicated plaster.

Lidocaine Grünenthal medicated plaster contains propylene glycol, methyl parahydroxybenzoate and propyl parahydroxybenzoate
The plasters contain propylene glycol (E1520) which may cause skin irritation. In addition it contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions. The allergic reactions may sometimes occur after you have been using the plaster for some time.

3. How to use Lidocaine Grünenthal medicated plaster

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

The usual daily dose is to use between one and three plasters of the size of the painful areas of your skin. Lidocaine Grünenthal medicated plaster may be cut into smaller pieces to fit the affected area. You should not use more than 3 plasters at the same time.

The plasters should be removed after 12 hours of use, so that you have a 12 hour period with no plaster. You can choose to apply Lidocaine Grünenthal medicated plaster during the day or during the night.

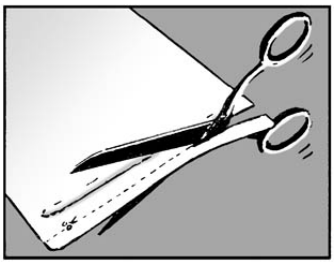
Usually, you will feel some pain relief on the first day you use the plaster, but it may take up to 2 - 4 weeks until the full pain-relief effect of Lidocaine Grünenthal medicated plaster is seen. If after that time you still have a lot of pain, please talk to your doctor because the benefits of the treatment must be weighed against potential risks (see Section 2 under 'Warnings and precautions').

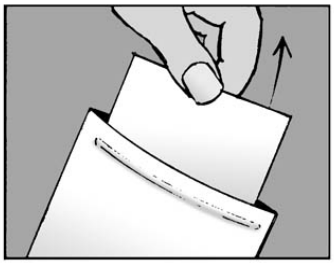
Your doctor will check how well Lidocaine Grünenthal medicated plaster is working at regular intervals.

Before you stick Lidocaine Grünenthal medicated plaster on the affected area
- If the painful area of skin has hairs on it, you can cut the hairs off using scissors. Do not shave them off.
- The skin should be clean and dry.
- Creams and lotions may be used on the affected skin during the period when you are not wearing the plaster.
- If you have had a recent bath or shower, you should wait until your skin cools before using the plaster.

Sticking the plaster on

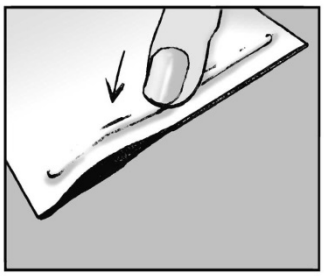
Step 1: open the sachet and remove one or more plasters





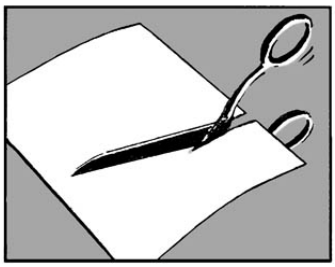
- tear open or cut the sachet along the dotted line
- when using scissors, be careful not to damage the plasters
- take out one or more plasters depending on the size of the painful area on your skin

Step 2: close the sachet



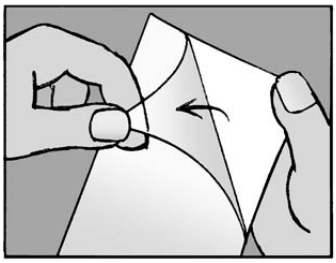
- close the sachet tightly after use
- the plaster contains water, and will dry out if the sachet is not closed properly

Step 3: cut the plaster, if necessary



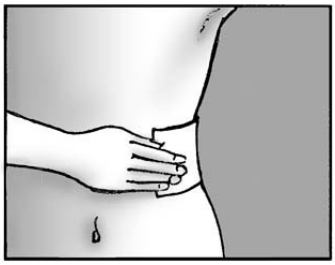
- if required, cut the plaster to the required size to fit the painful area of skin before removing the liner

Step 4: remove the liner



- remove the transparent liner from the plaster
- try not to touch the sticky part of the plaster

Step 5: apply the plaster and press it firmly onto the skin



- apply up to three plasters to the painful area of skin
- press the plaster onto your skin
- press for at least 10 seconds to make sure the plaster sticks firmly
- make sure that all of it sticks to your skin, including the edges

Leave the plaster on for 12 hours only

It is important that Lidocaine Grünenthal medicated plaster is in contact with your skin for only 12 hours. For example, if you have more pain at night you might want to apply the plaster at 7pm in the evening and remove it at 7am in the morning.

If you have more pain during the day than at night you might want to apply Lidocaine Grünenthal medicated plaster at 7am in the morning, and remove it at 7pm in the evening.

Bathing, showering and swimming
If at all possible contact with water should be avoided whilst using Lidocaine Grünenthal medicated plaster. Bathing, showering or swimming can be done in the time period when you are not wearing the plaster. If you have had a recent bath or shower, you should wait until your skin cools before using the plaster.

If the plaster comes off
Very rarely the plaster might fall off, or come unstuck. If it does, try sticking it back on the same area. If it does not stay on, remove it and put a new plaster on the same area.

How to remove Lidocaine Grünenthal medicated plaster
When changing the plaster, remove the old plaster slowly. If it does not come off easily, you can soak it in warm water for a few minutes before removing the plaster.

If you forget to remove the plaster after 12 hours
As soon as you remember, remove the old plaster. A new plaster can be used again after 12 hours.

If you use more plasters than you should
If you use more plasters than necessary or wear them for too long, this may increase the risk of getting side effects.

If you forget to use Lidocaine Grünenthal medicated plaster
After the 12 hour period with no plaster, if you have forgotten to use a new plaster, you should stick on a new plaster as soon as you remember.

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

4. Possible side effects

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

Important side effects or symptoms to look out for and what to do if you are affected:
If irritation or burning sensation occurs whilst you are using the plaster, the plaster should be removed. The area of irritation should remain plaster free until the irritation stops.

Other side effects that may occur:
Very common (may affect more than 1 in 10 people): Skin conditions at or around the site of plaster application, which may include redness, rash, itching, burning, dermatitis, and small blisters.

Uncommon (may affect up to 1 in 100 people): Skin injury and skin wounds.

Very rare (may affect up to 1 in 10,000 people): Open wound, severe allergic reaction and allergy.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Grünenthal medicated plaster

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 sachet and carton after EXP. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.
After first opening: Keep the sachet tightly closed.

Shelf-Life after first opening of the sachet: 14 days.

Do not use this medicine if you notice that the sachet has been damaged. If this has occurred, the plasters may dry out and become less sticky.

How to throw away Lidocaine Grünenthal medicated plaster
Used plasters still contain active ingredient, which may be harmful to others. Fold the used plasters in half, with the sticky sides together and throw them away so that they are out of the reach of children.

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 Lidocaine Grünenthal medicated plaster contains
- The active substance is lidocaine.
- Each 10 cm x 14 cm plaster contains 700 mg lidocaine (5% w/w).
- The other ingredients in the plaster (excipients) are glycerol, liquid sorbitol, carmellose sodium, propylene glycol (E1520), urea, heavy kaolin, tartaric acid, gelatin, polyvinyl alcohol, aluminium glycinate, disodium edetate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), polyacrylic acid, sodium polyacrylate, purified water.

Backing fabric and release liner: polyethylene terephthalate (PET)

What Lidocaine Grünenthal medicated plaster looks like and contents of the pack
The medicated plaster is 14 cm long and 10 cm wide. It is white and made of fleece fabric marked with "lidocaine 5%". The plasters are packed in re-sealable sachets, each containing 5 plasters.

Each carton contains 5, 10, 20, 25 or 30 plasters packed in 1, 2, 4, 5 or 6 sachets, respectively. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Grünenthal Limited
TOR Building,
Saint Cloud Way,
Maidenhead,
Berkshire, SL6 8BN
United Kingdom

Manufacturer:
Grünenthal GmbH
Zieglerstrasse 6
D-52078 Aachen
Germany

Other formats:
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:

Product name	**Reference number**
Lidocaine Grünenthal 700 mg medicated plaster	PL 21727/0075

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

This leaflet was last revised in 12/2023