

(lidocaine)

Patient Information Leaflet

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.

Your medicine is called Versatis 5% Medicated Plasters but will be referred to as Versatis throughout the leaflet.

In this leaflet:

- 1 What Versatis is and what it is used for
- 2 What you need to know before you use Versatis
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1 What Versatis is and what it is used for

Versatis contains lidocaine, a local analgesic, which works by reducing the pain in your skin.

You have been given Versatis to treat a painful skin condition called postherpetic neuralgia. This is generally characterised by localised symptoms such as burning, shooting or stabbing pain.

2 What you need to know before you use Versatis**Do not use Versatis**

- 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 Versatis.

If you have severe liver disease, or severe heart problems, or severe kidney problems, you should talk to your doctor before using Versatis. Versatis 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

Versatis 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 Versatis

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.

Versatis should not be used in pregnancy unless clearly necessary. There are no studies of the plaster in breast-feeding women. When using Versatis, 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 Versatis on the ability to drive and use machines is unlikely. Therefore you may drive or operate machinery whilst using Versatis.

Versatis 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 Versatis

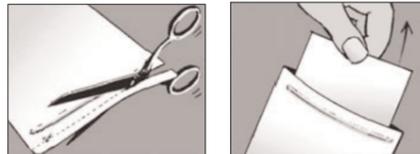
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual daily dose is to use between one and three plasters of the size of the painful areas of your skin. Versatis 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 Versatis 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 Versatis 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 Versatis is working at regular intervals.

Before you stick Versatis 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

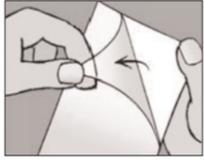
Step 2: close the sachet

- 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 Versatis 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 Versatis 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 Versatis. 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 Versatis

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 Versatis

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. 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.

Very common side effects which may affect more than 1 in 10 people are listed below.

These include skin conditions at or around the site of plaster application, which may include redness, rash, itching, burning, dermatitis, and small blisters.

Uncommon side effects which may affect up to 1 in 100 people are listed below.

Skin injury and skin wounds

Very rare side effects which may affect up to 1 in 10,000 people are listed below.

Open wound, severe allergic reaction and allergy.

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 the Yellow Card Scheme at: 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 Versatis

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN
- Keep the sachet tightly closed.
- Do not refrigerate or freeze.
- After first opening of the sachet, the plasters must be used within 14 days.
- Do not use after the expiry date which is stated on the sachet label and on the carton.
- 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 Versatis

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.

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

6 Further Information

What Versatis contains

- The active substance is lidocaine.
- Each 10 cm x 14 cm plaster contains 700 mg (5% w/w) lidocaine
- The other ingredients in the plaster are glycerol, liquid sorbitol crystallisable, 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: polyethylene terephthalate (PET).
Release liner: polyethylene terephthalate.

What Versatis looks like and contents of the pack

White medicated plasters made of a fleece fabric marked with lidocaine 5%. The plasters are packed in re-sealable sachets, each containing 5 plasters. Each carton contains 30 plasters packed in 6 sachets.

Manufacturer and Licence Holder

Versatis is manufactured by Grunenthal GmbH, Zieglerstrasse 6 -52078 Aachen, Germany and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE

Versatis is a registered trademark of Grünenthal GmbH.

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Tel: 01527 505414 for help.