

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Versatis is and what it is used for
2. Before you use Versatis
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Versatis® 5% medicated plaster

Lidocaine



1. WHAT VERSATIS IS AND WHAT IT IS USED FOR

Versatis contains lidocaine which works by reducing the pain in your skin.

It is used to treat the pain caused by post-herpetic neuralgia. After you have had shingles, postherpetic neuralgia may develop due to damage to the nerves in your skin. This can be very painful and the pain can last for a long time.

2. BEFORE YOU USE VERSATIS

Do not use Versatis

- if you are hypersensitive (allergic) to lidocaine or any of the other ingredients of Versatis.
- if you have had an allergic reaction to other products which are similar to lidocaine, such as bupivacaine, etidocaine, mepivacaine or prilocaine.

Take special care with 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 not be used on injured skin or open wounds. It 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.

Versatis has not been studied in patients under 18 years of age. Therefore it is not recommended for use in this patient population.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Versatis should not be used in pregnancy unless clearly necessary. Ask your doctor or pharmacist for advice before taking any medicine. 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.

Important information about some ingredients of Versatis

The plasters contain propylene glycol which may cause skin irritation. In addition it contains methyl parahydroxybenzoate and propyl parahydroxybenzoate 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 Versatis exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual daily dose is to use between one and three plaster(s) 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. 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

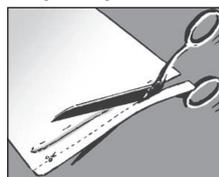
effect of Versatis is seen. If after that time you still have a lot of pain, please talk to your doctor.

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, but the skin should be clean and dry before the plaster is stuck onto your skin.
- If you have had a recent bath or shower, you should wait until your skin cools before using the plaster.

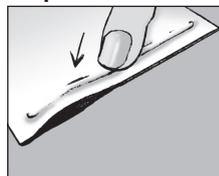
Sticking the plaster on

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



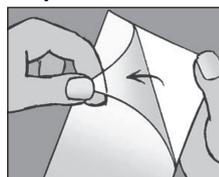
- close the sachet tightly after use
- the plaster contains water, and will dry out if the sachet is not closed properly

Step 3: cut the plaster, if necessary



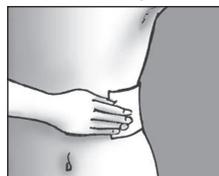
- if required, cut the plaster to the required size to fit the painful area of skin before removing the liner

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.

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

How to remove and dispose of 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. 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 and pets. You should follow local guidelines for domestic waste when throwing away used or unused plasters. Ask your pharmacist how to dispose of medicines no longer required. Do not flush them down the toilet.

4. POSSIBLE SIDE EFFECTS

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. 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 person in 10 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 between 1 person in 100 and 1 in 1,000 are listed below.

Skin injury and skin wounds.

Very rare side effects which may affect less than 1 person in 10,000 are listed below.

Open wound, severe allergic reaction and allergy.

5. HOW TO STORE VERSATIS

- Store the plasters in the original sachet, and close the sachet tightly after first opening. After opening the sachet, the plasters should be used within 14 days.

- Do not use Versatis after the expiry date which is stated on the sachet and carton. The expiry date refers to the last day of that month.

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

- Do not refrigerate or freeze.

- Keep out of the reach and sight of children.

6. FURTHER INFORMATION

What Versatis contains

- The active substance is lidocaine.

- The other ingredients are glycerol, liquid sorbitol (E420), carmellose sodium (E466), propylene glycol (E1520), urea, heavy kaolin, tartaric acid (E334), 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 Versatis 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 patch 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 Ltd
Regus Lakeside House
1 Furzeground Way
Stockley Park East
Uxbridge
Middlesex UB11 1BD
United Kingdom

Manufacturer responsible for batch release:

Grünenthal GmbH
Zieglerstrasse 6
52078 Aachen
Germany

For any information about this medicinal product, please contact the Marketing Authorisation Holder.

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
Versatis 5% medicated plaster	PL 21727/0016

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

This leaflet was last approved in 11/2006