

VERSATIS[®] 5% w/w Dermal Patch

Lidocaine (Lignocaine)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Read this leaflet carefully before you start using this medicine.

This leaflet answers some common questions about VERSATIS Dermal Patch.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using VERSATIS Dermal Patch against the benefits they expect it will have for you.

If you have any concerns about using this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What VERSATIS Dermal Patch is used for

VERSATIS Dermal Patch contains lidocaine, a local anaesthetic, which works by reducing the pain in your skin.

You have been given it to treat a painful skin condition called post-herpetic neuralgia. This is the pain which persists after Herpes Zoster (Shingles) infection. It is generally characterised by localised symptoms such as burning, shooting or stabbing pain.

Ask your doctor if you have any questions about why VERSATIS Dermal Patch has been prescribed for you.

Your doctor may have prescribed it for another reason.

VERSATIS Dermal Patch is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you apply VERSATIS Dermal Patch

When you must not use it

Do not use VERSATIS Dermal Patch if you have an allergy to:

- any medicine containing lidocaine
- any of the ingredients listed at the end of this leaflet, especially methyl hydroxybenzoate and propyl hydroxybenzoate
- any other medicines similar to lidocaine such as bupivacaine, etidocaine, mepivacaine or prilocaine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use VERSATIS Dermal Patch:

- on injured skin or open wounds
- on the eyes or mouth
- on unhealed shingles blisters

Do not give VERSATIS Dermal Patch to children.

Safety and effectiveness in children younger than 18 years has not been established.

Do not use VERSATIS Dermal Patch if the expiry date (Exp.) printed on the pack has passed.

Do not use VERSATIS Dermal Patch if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If the package has become damaged, the dermal patches may dry out and become less sticky.

Before you start to use it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- severe liver disease
- severe kidney disease
- severe heart problems

Tell your doctor if you are pregnant or plan to become pregnant or are breast feeding.

Your doctor can discuss the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start using VERSATIS Dermal Patch.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by VERSATIS Dermal Patch, or may affect how well it works. These include:

- some drugs used to slow the heart, including tocainide and mexiletine
- other local anaesthetics such as bupivacaine, etidocaine, mepivacaine or prilocaine.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using VERSATIS Dermal Patch.

How to apply VERSATIS Dermal Patch

Follow all directions given to you by your doctor or pharmacist carefully.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much to use

The daily dose is between one and three patches depending on the size of the painful area of your skin.

VERSATIS Dermal Patch may be cut into smaller pieces to fit the affected area.

You should not use more than 3 patches at the same time.

VERSATIS Dermal Patches should be worn for no more than 12 hours per day. Applying the patches for a longer time or using more than 3 patches per day could cause serious reactions.

The patches should be removed after 12 hours of use, so that you have a 12 hour period with no patch in place.

Usually, you will feel some pain relief on the first day you use the patch, but it may take up to 2 - 4 weeks until the full pain-relief effect of VERSATIS Dermal Patch is seen. If after that time you still have a lot of pain, talk to your doctor because the benefits of the treatment must be weighed against potential risks. Your doctor will check how well VERSATIS Dermal Patch is working at regular intervals.

Before you apply VERSATIS

Dermal Patch to the affected area

- Cut any hairs on the affected skin using scissors. Do not shave hairs off.
- Ensure the skin is clean and dry.

Creams and lotions may be used on the affected skin during the period when you are not wearing the patch.

- Allow your skin to cool off after a bath or shower.

VERSATIS Dermal Patch should only be used on the areas of skin after the shingles rash has healed. It should not be used on or near the mouth.

Avoid contact of VERSATIS Dermal Patch with the eye. If contact occurs, immediately wash the eye with water or saline and protect it until sensation returns.

Avoid the use of external heat sources, such as heating pads or electric blankets, as the effect of this has not been studied. Local heat may alter the absorption of lidocaine from the patch.

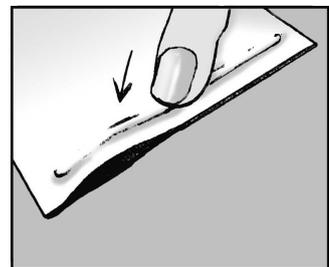
How to apply VERSATIS Dermal Patch

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



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

Step 2: close the sachet



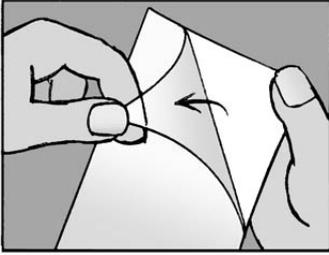
- close the sachet tightly after use
- the patch contains water, and will dry out if the sachet is not closed properly.

Step 3: cut the patch, if necessary



- if required, cut the patch 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 patch
- try not to touch the sticky part of the patch

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



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

Leave the patch on for 12 hours only



It is important that VERSATIS Dermal Patch 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 patch 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 the patch 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 wearing VERSATIS Dermal Patch. Bathing, showering or swimming can be done in the time period when you are not wearing the patch. If you have had a recent bath or shower, you should wait until your skin cools before applying the patch.

If the patch comes off

Very rarely the patch 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 patch on the same area.

How to remove VERSATIS Dermal Patch

When changing the patch, remove the old patch slowly. If it does not come off easily, you can soak it in warm water for a few minutes before removing it.

If you forget to remove the patch after 12 hours

As soon as you remember, remove the old patch. A new patch can be used again after 12 hours.

If you forget to use VERSATIS Dermal Patch

If it is almost time for you to apply the next patch dose, skip the one you missed and apply the next patch when you are meant to.

Otherwise, apply a new patch as soon as you remember, and then go back to your normal schedule.

Do not use a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

How long to use VERSATIS Dermal Patch for

Continue using it for as long as the doctor tells you.

If you use too much VERSATIS Dermal Patch (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) if you think you or anyone else may have used too much VERSATIS Dermal Patch. Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include: dizziness, vomiting, drowsiness, taste disturbances or loss of taste, seizures, dilated pupils, a low heart beat, changes in the way the heart beats (faster, slower, irregular), and shock.

While you are using VERSATIS Dermal Patch

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are using VERSATIS Dermal Patch.

If irritation or burning sensation occurs whilst you are using the patch, it should be removed.

The area of irritation should remain patch free until the irritation stops.

Even a used VERSATIS Dermal Patch contains a large amount of lidocaine. A small child or pet could suffer serious adverse effects from chewing or swallowing a new or used patch. Store and dispose of patches out of the reach of children, pets and others. Never re-use a patch.

If you become pregnant while taking VERSATIS Dermal Patch, tell your doctor.

Keep all your doctor's appointments so that your progress can be checked.

Things you must not do

Do not stop using VERSATIS Dermal Patch, or change the dose, without checking with your doctor.

Do not use VERSATIS Dermal Patch to treat any other conditions unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using VERSATIS Dermal Patch.

This medicine helps most people with your condition, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Tell your doctor if you notice any of the following and they worry you:

Skin conditions at or around the patch application site, which may include

- redness
- rash
- itching
- burning
- dermatitis
- small blisters

The above list includes some of the very common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- skin injury
- skin wound

The above list includes serious side effects that may require medical attention. These side effects are uncommon.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe allergic reaction and allergy
- open wound

The above is a very serious side effect. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using VERSATIS Dermal Patch

Storage

Keep VERSATIS Dermal Patch where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not refrigerate or freeze.

After first opening: Keep the sachet tightly closed.

After opening the sachet, the patches should be used within 14 days.

Do not store VERSATIS Dermal Patch or any other medicine in the bathroom or near a sink.

Do not leave VERSATIS Dermal Patch in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop using VERSATIS Dermal Patch,

or your medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

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

Product description

What it looks like

VERSATIS Dermal Patch is 14 cm long and 10 cm wide. It is white and made of fleece fabric marked with "lidocaine 5%". The patches are packed in re-sealable sachets, each containing 5 patches.

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

Ingredients

The active substance is lidocaine (also known as lignocaine).

Each 10 cm x 14 cm patch contains 700 mg (5% w/w) lidocaine.

The other ingredients in the patch are:

Self Adhesive Layer:
glycerol, sorbitol solution (70 per cent) (crystallising), carmellose sodium, propylene glycol, urea, kaolin-heavy, tartaric acid, gelatin, polyvinyl alcohol, aluminium glycinat, disodium edetate, methyl hydroxybenzoate, propyl hydroxybenzoate, polyacrylic acid, sodium polyacrylate, water – purified

Backing fabric and release liner:
Polyethylene terephthalate (PET)

Sponsor:

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