

VERSATIS[®] dermal patch

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using VERSATIS[®] dermal patch?

VERSATIS[®] dermal patch contains the active ingredient lidocaine.

VERSATIS[®] dermal patch is used to treat a painful skin condition called postherpetic neuralgia.

For more information, see Section [1. Why am I using VERSATIS[®] dermal patch?](#) in the full CMI.

2. What should I know before I use VERSATIS[®] dermal patch?

Do not use if you have ever had an allergic reaction to lidocaine, methyl hydroxybenzoate, propyl hydroxybenzoate or any of the ingredients listed at the end of the CMI. Do not use if you have an allergy to other medicines similar to lidocaine such as bupivacaine, etidocaine, mepivacaine or prilocaine.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use VERSATIS[®] dermal patch?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VERSATIS[®] dermal patch and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use VERSATIS[®] dermal patch?

- The daily dose is between one and three patches depending on the size of the painful area of your skin.
- VERSATIS[®] dermal patches should be worn for no more than 12 hours per day.

More instructions can be found in Section [4. How do I use VERSATIS[®] dermal patch?](#) in the full CMI.

5. What should I know while using VERSATIS[®] dermal patch?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentists, pharmacists, surgeons or anesthetists you visit that you are using VERSATIS[®] dermal patch.• Remove the patch if any irritation or burning sensation occurs while using the patch.• If you become pregnant while taking VERSATIS[®] dermal patch call your doctor straightaway.• Keep all your doctor's appointments so your progress can be tracked.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change the dose without checking with your doctor.• Do not use this medicine to treat any other conditions unless your doctor tells you to.• Do not give this medicine to anyone else, even if they have the same condition as you.• Never re-use a patch.
Driving or using machines	<ul style="list-style-type: none">• This medicine is not expected to affect your ability to drive a car or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.• After first opening the sachet, keep the sachet tightly closed. Patches should be used within 14 days of opening the sachet.

For more information, see Section [5. What should I know while using VERSATIS[®] dermal patch?](#) in the full CMI.

6. Are there any side effects?

VERSATIS[®] dermal patch may cause the following skin conditions at or around the patch application site: redness, rash, itching, burning, dermatitis, small blisters.

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of the following of these serious side effects: Allergic reaction (symptoms 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); open wound; skin injury; skin wound.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

VERSATIS® dermal patch

Active ingredient: *lidocaine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VERSATIS® dermal patch. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VERSATIS® dermal patch.**

Where to find information in this leaflet:

- [1. Why am I using VERSATIS® dermal patch?](#)
- [2. What should I know before I use VERSATIS® dermal patch?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use \[medicine name\]?](#)
- [5. What should I know while using VERSATIS® dermal patch?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using VERSATIS® dermal patch?

VERSATIS® dermal patch contains the active ingredient **lidocaine**. Lidocaine is a local anaesthetic, which works by reducing the pain in your skin.

VERSATIS® dermal patch is used to treat a painful skin condition called **postherpetic 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.

2. What should I know before I use VERSATIS® dermal patch?

Warnings

Do not use VERSATIS® dermal patch:

- if you are allergic to lidocaine, methyl hydroxybenzoate, propyl hydroxybenzoate or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- if you are allergic to any other medicines similar to lidocaine such as bupivacaine, etidocaine, mepivacaine or prilocaine.
- on injured skin or on open wounds.
- on the eyes or mouth.
- on unhealed shingles blisters.

Check with your doctor if you:

- severe liver disease.
- severe kidney disease.

- severe heart problems.
- have any other medical conditions.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. If you become pregnant while taking VERSATIS® dermal patch, tell your doctor.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children

Do not give VERSATIS® dermal patch to children.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with VERSATIS® dermal patch and affect how 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VERSATIS® dermal patch.

4. How do I use VERSATIS® dermal patch?

How much VERSATIS® dermal patch 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.
- Follow the instructions provided and use VERSATIS® dermal patch until your doctor tells you to stop.

How long to use VERSATIS® dermal patch for

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

How to use VERSATIS® dermal patch

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.
- Allow your skin to cool off after a bath or shower.
- Creams and lotions may be used on the affected skin during the period when you are not wearing the patch.

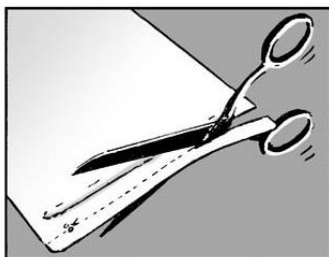
VERSATIS® dermal patch should only be used on the areas of skin after the shingles rash has healed. It should not be used on or near the mouth.

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.

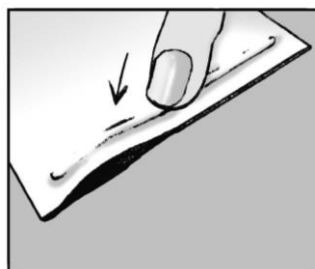
How to apply the patch:

Step 1: Open the sachet and remove one or more patches.



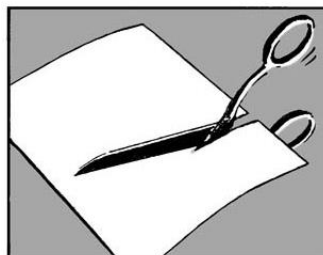
- Tear open or cut the sachet along the dotted line.
- When using scissors, be careful not to damage the patches.
- Take out one or more patches depending on the size of the painful area on your skin.

Step 2: Close the sachet.



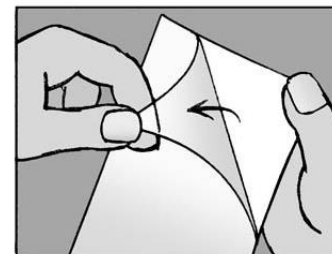
- Close the sachet tightly after use.
- The patch contains water and will dry out if the sachet is not closed properly.

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.

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.

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

VERSATIS® dermal patch should be used regularly at the same time each day.

If you miss your dose at the usual time and it is almost time for you to apply the next patch dose, skip the one you missed and apply the next patch dose 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 take a double dose to make up for the dose you missed.

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

If you use too much VERSATIS® dermal patch

If you think that you have used too much VERSATIS® dermal patch, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs or symptoms of discomfort or poisoning.

Signs or symptoms of an overdose may include:

- dizziness
- vomiting
- drowsiness
- taste disturbances or loss of taste
- seizures
- dilated pupils
- a low heartbeat
- changes in the way the heart beats (faster, slower, irregular);
- shock.

5. What should I know while using VERSATIS® dermal patch?

Things you should 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.

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

Call your doctor straight away if you:

- Become pregnant while taking VERSATIS® dermal patch.

Remind any doctor, dentist, pharmacist, surgeons or anesthetists you visit that you are using VERSATIS® dermal patch.

Things you should not do

- Do not stop using this medicine 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.
- Never re-use a patch.

Driving or using machines

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

Looking after your medicine

- **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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children and pets cannot reach it.

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.

When to discard your medicine (as relevant)

Do not use VERSATIS® dermal patch if the packaging is torn or shows signs of tampering. If the package has become damaged, the dermal patches may dry out and become less sticky.

Do not use VERSATIS® dermal patch if the expiry date (Exp.) printed on the pack has passed.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Skin conditions at or around the patch application site which may include: <ul style="list-style-type: none"> ○ redness ○ rash ○ itching ○ burning ○ dermatitis ○ small blisters 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Allergic reaction. Symptoms of an allergic reaction may include: <ul style="list-style-type: none"> ○ 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. • Open wound. • Skin injury. • Skin wound. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

There is no evidence this medicine is addictive.

What VERSATIS® dermal patch contains

Active ingredient (main ingredient)	lidocaine.
Other ingredients (inactive ingredients)	Self-Adhesive Layer: <ul style="list-style-type: none">• glycerol• sorbitol solution (70 per cent) (crystallising)• carmellose sodium• propylene glycol• urea• kaolin-heavy• tartaric acid• gelatin• polyvinyl alcohol• aluminium glycinate• disodium edetate• methyl hydroxybenzoate• propyl hydroxybenzoate• polyacrylic acid• sodium polyacrylate• water – purified. Backing fabric and release liner: <ul style="list-style-type: none">• Polyethylene terephthalate (PET).
Potential allergens	<ul style="list-style-type: none">• methyl hydroxybenzoate.• propyl hydroxybenzoate.

Do not take this medicine if you are allergic to any of these ingredients.

What VERSATIS® dermal patch looks like

VERSATIS® lidocaine 5% w/w dermal patch (AUST R 175178) 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.

Registered pack sizes are cartons containing 5, 10, 20, 25 or 30 patches packed in 1, 2, 4, 5 or 6 sachets respectively. Not all pack sizes may be marketed.

Who distributes VERSATIS® dermal patch

Sponsor:

Seqirus Pty Ltd

ABN: 26 160 735 035

63 Poplar Road

Parkville VIC 3052

Australia

Telephone: 1800 642 865

www.csseqirus.com.au

Distributor:

Seqirus (Australia) Pty Ltd

Melbourne, Australia

Manufactured and licensed by:

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Grünenthal GmbH used by Seqirus

as authorised user.

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