

NERVODERM® 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 NERVODERM® Dermal Patch.

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

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 NERVODERM® Dermal Patch is used for

This medicine is used to relieve medically diagnosed post-shingles nerve pain (post-herpetic neuralgia), which may be felt as burning, stabbing, shooting pains at or near the skin surface that may be accompanied by increased sensitivity to touch, heat or cold.

NERVODERM® Dermal Patch provides pain relief in 2 ways:

- contains lidocaine, which absorbs into the skin to reduce the transmission of pain impulses from nerve endings in your skin and relieve pain.
- the hydrogel patch forms a protective barrier providing a soothing effect at the site of application.

NERVODERM® Dermal Patch is available to buy from a pharmacy.

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 NERVODERM® Dermal Patch

When you must not use it

Do not use NERVODERM® 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
- other local anaesthetic 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 NERVODERM® Dermal Patch:

- on injured skin or open wounds
- on the eyes or mouth
- on unhealed areas of skin, for example unhealed blisters

Do not give NERVODERM® Dermal Patch to children.

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

Do not use NERVODERM® Dermal Patch after the expiry date printed on the pack or 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.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to use it

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

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

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

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

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

Taking other medicines

Tell your doctor or pharmacist 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 NERVODERM® 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, prilocaine or lidocaine.

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

How to apply NERVODERM® Dermal Patch

Follow the below directions carefully. Ask your pharmacist if you have any questions.

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 NERVODERM® patches depending on the size of the painful area of your skin. Remember you should not use other products that contain lidocaine at the same time.

NERVODERM® 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.

NERVODERM® 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 NERVODERM patches per day could cause serious reactions. Remember you should not use other products that contain lidocaine at the same time.

Wait 12 hours after removing patches before applying new patches.

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 NERVODERM Dermal Patch is seen. If after that time you still have a lot of pain, talk to your doctor or pharmacist because the benefits of the treatment must be weighed against potential risks.

Before you apply NERVODERM® Dermal Patch to the affected area

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

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

- Allow your skin to cool off after a bath or shower before you apply the patch.

NERVODERM® Dermal Patch should not be used on unhealed areas of skin for example unhealed blisters. It should not be used on or near the mouth.

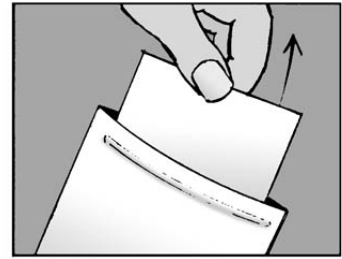
Avoid contact of NERVODERM® Dermal Patch with the eye. If contact occurs, immediately wash the eye with water or saline (salt solution) and protect it until sensation returns.

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

How to apply NERVODERM® Dermal Patch

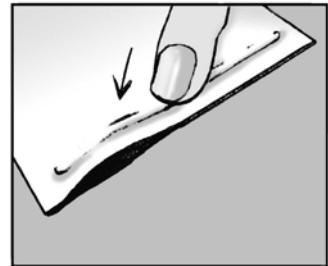
NERVODERM® Dermal Patch is for external use only

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

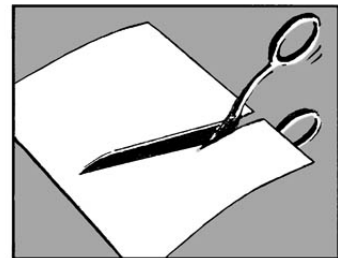
Step 2: Close the sachet



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

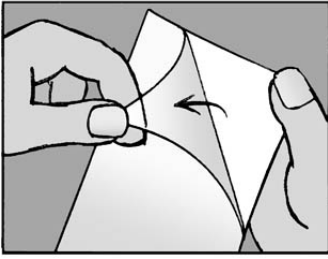
Step 3: Cut the patch, if necessary

- If required, cut the patch to



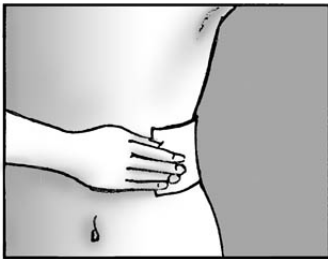
the required size to fit the painful area before removing the liner.

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 affected area



- Apply up to 3 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 NERVODERM[®] Dermal Patch is only in contact with your skin for 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.

Wait 12 hours after removing patches before applying new patches.

Bathing, showering and swimming

If at all possible contact with water should be avoided whilst wearing NERVODERM[®] Dermal Patch. Bathing, showering or swimming can be done 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 NERVODERM[®] 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 NERVODERM[®] 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 NERVODERM[®] Dermal Patch for

Because of the way NERVODERM Dermal Patch works, relief may not occur immediately and improvement may be gradual. The time required varies from person to person. If a lot of pain persists after using NERVODERM[®] Dermal Patch for 2 to 4 weeks, see your doctor or pharmacist.

Continue using it for as long as your doctor or pharmacist tells you.

If you use too much NERVODERM[®] 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 NERVODERM[®] 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 NERVODERM[®] Dermal Patch

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are using NERVODERM[®] 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 NERVODERM® Dermal Patch contains a large amount of lidocaine. A small child or pet could suffer serious side 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. See also "After using NERVODERM® Dermal Patch" below.

If you become pregnant while taking NERVODERM® Dermal Patch, tell your doctor or pharmacist.

Things you must not do

Do not use more than 3 NERVODERM® Dermal patches at the same time.

Do not use NERVODERM® Dermal Patch to treat any other conditions.

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 NERVODERM® 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 or pharmacist 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 or pharmacist 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 or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- severe allergic reaction and allergy
- open wound

The above list includes very serious side effects. 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 or pharmacist if you notice anything that is making you feel unwell.

After using NERVODERM® Dermal Patch

Storage

Keep NERVODERM® Dermal Patch in the box until it is time to use it.

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 NERVODERM® Dermal Patch or any other medicine in the bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor or pharmacist tells you to stop using NERVODERM® Dermal Patch, or your medicine has passed its expiry date, ask your pharmacist what to do with any left over patches.

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

NERVODERM® 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 or 30 patches packed in 1, 2 or 6 sachets, respectively.

Ingredients

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

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

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 glycinate, 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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