

Neupro®

Transdermal Patches

pronounced ("NEW-pro")

Contains the active ingredient rotigotine ("roe-TIG-oh-teen")

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Neupro.

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

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

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

Keep this leaflet with the medicine. You may need to read it again.

What Neupro is used for

Neupro is used in the treatment of Parkinson's disease and Restless Legs Syndrome (RLS).

Parkinson's disease

This is a disease of the nervous system that mainly affects body movement. The main symptoms are shaking (tremor), muscle stiffness and slow unsteady movement. If untreated, Parkinson's disease can cause difficulty in performing daily activities.

Parkinson's disease is caused by the brain not making enough of a chemical called dopamine. Dopamine helps the brain to control muscle movement. When too little dopamine is produced slowness of movement results.

Restless Legs Syndrome (RLS)

RLS is a condition characterised by unpleasant sensations in the legs and the irresistible urge to move in an effort to relieve these feelings. There is a sense of uneasiness, restlessness, and itching often accompanied by twitching and pain in the legs when sitting or lying down, especially in bed at night. Occasionally the arms may also be affected. RLS is thought to be due to insufficient dopamine levels in the brain.

Neupro belongs to a group of medicines called non-ergot dopamine agonists which stimulate dopamine receptors in the brain to increase the effects of dopamine.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Before you use Neupro

When you must not take it

Do not use Neupro if you have an allergy to:

- rotigotine
- sodium metabisulfite
- any of the ingredients listed at the end of this leaflet.

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 Neupro if you need to have magnetic resonance imaging (MRI) (method to visualise internal organs and tissues of the body) or cardioversion (treatment of an abnormal heart rhythm).

You must take your Neupro patch off before the procedure. You can put a new patch on after the procedure.

Do not give this medicine to a child or adolescent.

The safety and effectiveness in children and adolescents has not been established.

Do not use this medicine if the packaging is torn or shows signs of tampering.

Do not use this medicine after the expiry date (Exp) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking Neupro, contact your doctor.

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 if you have or have had any other health problems or medical conditions, including:

- liver problems
- low blood pressure
- heart problems
- mental illness
- compulsive disorders such as gambling or a high sex drive
- problems with your sight.

Tell your doctor if you are pregnant or intend to become pregnant.

The effects of Neupro on pregnancy and the unborn child is not known. Neupro should not be used during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Neupro is not recommended if you are breastfeeding, as it is likely to reduce the amount of milk you produce. Neupro may also pass into your breast milk and affect your baby. If your doctor says you need to use Neupro, you should stop breastfeeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Neupro.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may interfere with Neupro. These include:

- some other medicines used to treat Parkinson's disease or Restless Legs Syndrome
- medicines used to treat depression or mental illness
- medicines used to calm you or help you sleep
- metoclopramide, a medicine used to treat nausea and vomiting.

These medicines may be affected by Neupro or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Neupro.

How to use Neupro

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

The dose varies from patient to patient. Your doctor may start you on a low dose of Neupro first and slowly increase the amount of medicine until you are taking enough to control your condition.

Parkinson's Disease

The usual starting dose is one 2 mg/24 hour patch or one 4 mg/24 hour patch daily. This dose will be increased gradually in steps of 2 mg/24 hours until the right (maintenance) dose for your needs is reached.

Restless Legs Syndrome

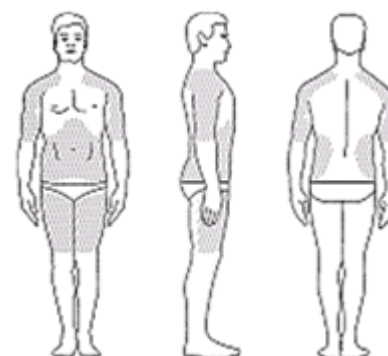
The usual starting dose is one 1 mg/24 hour patch. If necessary, this dose will be increased gradually in steps of 1 mg/24 hours until the right (maintenance) dose for your needs is reached. The maximum dose is 3 mg/24 hour.

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

Where to apply the patch

Put the sticky side of the patch onto clean, dry, healthy skin on one of the following areas at a time:

- shoulder
- upper arm
- belly
- thigh
- hip
- flank (your side, between your ribs and your hip).



To help avoid skin irritation, stick the patch onto a different area of skin each day (for example, on the right side of your body one day, then on the left side the next day and on your upper body one day, then on your lower body). You should not stick Neupro on the same area of skin twice within 14 days.

Things to remember

- You should put the patch where it will **not be rubbed by tight clothing** which could make it fall off.
- If you need to stick the patch to a hairy area of skin, you must **shave** the area at least **three days before** sticking the patch there.
- Do **not** stick the patch on **broken skin** or on skin that is **red, irritated or damaged**.
- Do **not** use **creams, oils, lotions, powders** or other **skin products** on the area of skin you will be sticking the patch on or near a patch you are already wearing. The patch may become loose.

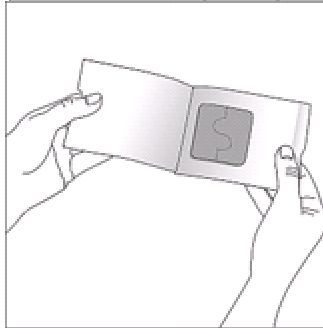
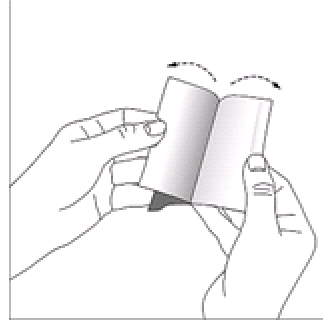
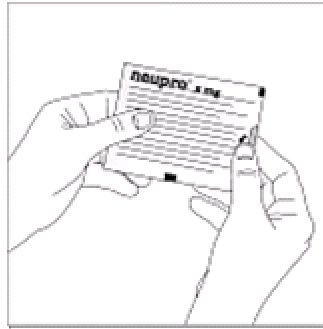
- **Bathing, showering and exercising** should not affect how Neupro works. There is no need to remove the patch when bathing, showering, swimming or exercising. Nevertheless, check that the patch has not fallen off after such activities.
- You should **avoid external heat** (for example excessive sunlight, saunas, hot baths, heating pads or hot-water bottles) on the area of the patch.
- If the patch has **irritated your skin**, you should **keep** that area of skin **covered from the sun**, as it may cause changes in the colour of the skin.

How to apply the patch

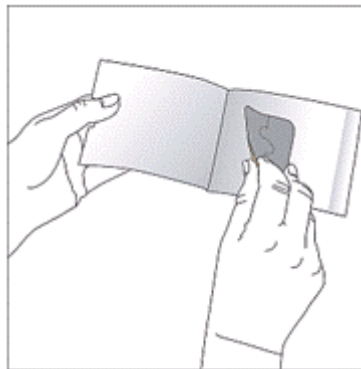
Each patch is packed in a sachet containing the medicine. You should stick Neupro onto your skin as soon as you have opened the sachet and removed the protective liner.

You should stick a Neupro patch onto the skin once a day. You should leave the patch on your skin for 24 hours and then replace it with a new one. Make sure that you take the old patch off before sticking on the new one. You should replace the patch at around the same time every day.

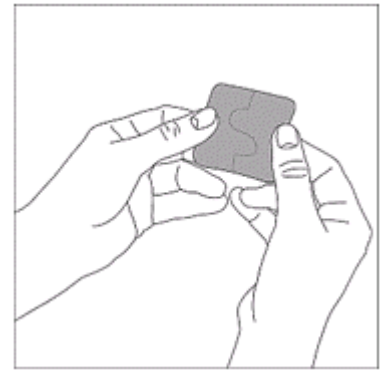
1. To open the sachet, hold the two sides of the sachet. Peel apart the foil and open the sachet.



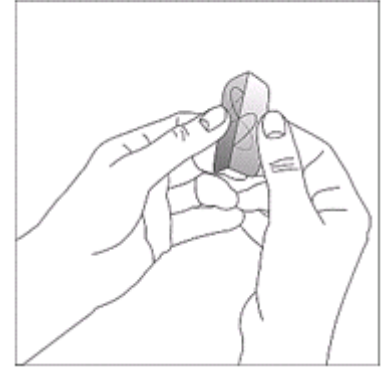
2. Take the patch out of the sachet.



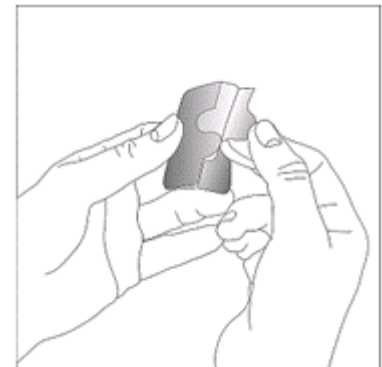
3. The sticky side of the patch is covered by a transparent protective liner. Hold the patch in both hands with the protective liner facing you.



4. Bend the patch in half so that the S-shaped break in the liner opens.



5. Peel off one side of the protective liner. Don't touch the sticky side of the patch with your fingers.



6. Hold the other half of the rigid protective liner and put the sticky surface of the patch onto your skin. Press the sticky side of the patch firmly into place.



7. Fold back the other half of the patch and remove the other side of the protective liner.



8. Press the patch down firmly with the palm of your hand for about 20 - 30 seconds to make sure the patch is touching the skin and that the edges stick well.

It is important to ensure you press the patch firmly for 20 - 30 seconds.



Wash your hands with soap and water immediately after handling the patch.

How to change the patch

Before you put on a new patch, slowly and carefully peel off the used patch.

Gently washing the area with warm water and mild soap should remove any adhesive that stays on your skin after you remove the patch.

You can also use a small amount of baby oil to remove any adhesive that won't wash off.

Do not use alcohol or other dissolving liquids such as nail polish remover or other solvents as these may irritate your skin.

If the patch falls off, a new patch should be applied for the rest of the day, then replace the patch at the same time as usual.

How long to use Neupro

Continue taking Neupro for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep using your medicine even if you feel well.

If you forget to use it

If you have forgotten to change the patch at the usual time of day, remove the old patch and use a new patch as soon as you remember.

If you have forgotten to stick on a new patch after removing the old one, use a new patch as soon as you remember. On the following day you should use a new patch at the usual time.

Do not use a double dose to make up for a forgotten dose.

If you use too much (overdose)

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

You may need urgent medical attention.

Using higher dosages of Neupro than your doctor has prescribed may cause nausea, vomiting, low blood pressure, fast heart beats, hallucinations, confusion or extreme sleepiness.

If you have used more patches than your doctor told you to, contact your doctor or the Poisons Information Centre immediately, and follow their advice on removal of patches.

While you are using Neupro

Things you must do

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are using Neupro.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Neupro.

Your doctor may ask you to stop taking Neupro before elective surgery or before some medical tests such as MRIs.

Tell your doctor immediately if you become pregnant while using this medicine.

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

Your doctor may do some tests, such as blood pressure monitoring or eye examinations from time to time to make sure the medicine is working, and to prevent unwanted side effects.

Some people taking Neupro to treat Restless Legs Syndrome, find their symptoms worsen. For example their symptoms may start earlier in the day than usual or be more intense.

Tell you doctor as soon as possible if your symptoms get worse while taking Neupro.

If you notice any problems with your vision, please contact your doctor.

Like with every patch or bandage, Neupro can cause skin reactions.

These are normally mild and usually affect only the area of skin the patch has been on. We recommend that you put the patch in a **different place every day**. You should **not** use the same area of skin within 14 days.

If you have a skin reaction which lasts for more than a few days, if a skin reaction becomes serious, or if the skin reaction spreads outside the area covered by the patch, please contact your doctor.

Avoid sunlight and solarium exposure on areas of skin showing any kind of skin reaction caused by Neupro.

Things you must not do

Do not use Neupro to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.

Do not stop using Neupro, or lower the dose, without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

If you stop taking it suddenly your condition may worsen or you may have unwanted side effects.

Do not cut Neupro patches into pieces.

Things to be careful of

Neupro may make you feel very drowsy and may cause some people to fall asleep suddenly without any apparent warning of sleepiness.

Make sure you know how Neupro affects you before you drive or operate machinery.

If you feel very drowsy, or experience episodes of falling asleep suddenly without feeling sleepy, do not drive or operate machinery or perform any other dangerous activities, and contact your doctor.

Be careful while drinking alcohol while taking Neupro.

Combining Neupro and alcohol can make you more drowsy. Your doctor may suggest you avoid alcohol while you are being treated with Neupro.

Side effects

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

This medicine helps most people with Parkinson's disease or restless legs syndrome, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea, vomiting
- dizziness or lightheadness when standing up quickly
- vertigo (sensation of spinning)
- feeling sleepy, falling asleep suddenly, being unable to sleep, nightmares, unusual dreams
- feeling weak or tired
- constipation
- skin irritations under the patch such as redness and itching
- swelling of legs and feet
- weight loss or weight increase
- dry mouth
- headache
- heartburn, stomach discomfort and pain
- increased sweating
- anxiety
- agitation
- hiccups
- abnormal movements including muscle twitching or spasms (which may occur in Parkinson's disease patients and may or may not resemble Parkinson's symptoms)

These are mild side effects of the medicine, and usually short-lived.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- seeing or hearing things that are not real (hallucinations)
- compulsive behaviour such as an unusual urge to carry out a certain activity including excessive gambling, repetitive meaningless actions, increased sex drive, compulsive spending, buying or eating
- confusion, disorientation
- falling, fainting
- rash, generalised itching
- visual disturbances such as seeing colours or lights or blurred vision

These may be serious side effects.

You may need urgent medical attention.

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

- psychotic disorders including abnormal thinking about reality and behaviour (paranoid psychosis)
- irregular heart beat, increased heart rate (palpitations)
- involuntary muscle spasms (seizure, convulsion)
- loss of consciousness
- 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.

These are very serious side effects.

You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Ask your doctor or pharmacist if you don't understand anything in this list.

After using Neupro

Storage

Keep your patches in their package until it is time to use them.

Store below 25°C. Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Neupro out of reach of children.

Disposal

Used patches still contain active ingredient, which may be harmful to others. Fold the used patch with the sticky side inwards. Put the patch in the original sachet and then throw it away safely, out of the reach of children.

Do not flush them down the toilet, nor place them in liquid waste disposal systems.

If your doctor tells you to stop using Neupro, or the patches have passed their expiry date, ask your pharmacist what to do with any patches left over.

Product description

What it looks like

Neupro is a transdermal patch that is available in four different strengths, 2 mg/24 h, 4 mg/24 h, 6 mg/24 h and 8 mg/24 h.

1 mg/24 h and 3 mg/24 h transdermal patches are not available in Australia.

The patches are thin and have three layers. They are square-shaped with rounded edges. The outside is tan-coloured and is imprinted with either Neupro 2 mg/24 h, Neupro 4 mg/24 h, Neupro 6 mg/24 h or Neupro 8 mg/24 h.

Neupro is available in cartons containing 28 patches, which are individually sealed in sachets.

Ingredients

The active ingredient is rotigotine.

- Neupro 2 mg/24 h releases 2 mg of rotigotine per 24 hours.
- Neupro 4 mg/24 h releases 4 mg of rotigotine per 24 hours.
- Neupro 6 mg/24 h releases 6 mg of rotigotine per 24 hours.
- Neupro 8 mg/24 h releases 8 mg of rotigotine per 24 hours.

The other ingredients are:

- povidone
- sodium metabisulfite
- DL- α -tocopherol
- ascorbyl palmitate
- silicone adhesives (BIO-PSA Q7-4301 and BIO-PSA Q7-4201).

Backing layer:

- polyester film
- silicone
- aluminium
- colour coated with a pigment layer (titanium dioxide, pigment yellow 95, pigment red 166) and imprinted (pigment red 144, pigment yellow 95, pigment black 7).

Protective liner:

- polyester film
- fluoropolymer.

Supplier

Neupro is supplied in Australia by:

UCB Pharma

A division of UCB Australia Pty Ltd
Level 1, 1155 Malvern Road
Malvern VIC 3144, Australia

Australian Registration Numbers:

Neupro 2 mg/24 h AUST R 131370
Neupro 4 mg/24 h AUST R 131381
Neupro 6 mg/24 h AUST R 131382
Neupro 8 mg/24 h AUST R 131383

This leaflet was prepared in August 2013.

Neupro is a registered trademark of UCB Pharma GmbH.