

Package leaflet: Information for the user

Neupro 3 mg/24 h transdermal patch Rotigotine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Neupro is and what it is used for
2. What you need to know before you use Neupro
3. How to use Neupro
4. Possible side effects
5. How to store Neupro
6. Contents of the pack and other information

1. What Neupro is and what it is used for

Neupro contains the active substance rotigotine. It belongs to a group of medicines called dopamine agonists which stimulate a certain type of cells and bind with dopamine receptors in the brain.

Neupro is used to treat **Restless Legs Syndrome (RLS)** in adults that can be associated with discomfort in your legs or arms, urge to move around, sleep disturbance, tiredness or sleepiness during the day. These symptoms are either alleviated or their duration is reduced with Neupro treatment.

2. What you need to know before you use Neupro

Do not use Neupro

- if you are **allergic** to **rotigotine** or any of the **other ingredients** of this medicine (listed in section 6).
- if you need to have **magnetic resonance** imaging (method to visualise internal organs and tissues of the body) or **cardioversion** (treatment of abnormal heart rhythm). You must take your Neupro patch off before such procedures. You can put a new patch on after the procedure.

Warnings and precautions

Talk to your doctor or pharmacist before using Neupro.

- This medicine may affect your **blood pressure**, so it should be measured regularly, especially at the beginning of your treatment.
- **Loss of consciousness** can occur. This can happen especially when you start using Neupro or when your dose is increased. Tell your doctor if you lose consciousness or feel dizzy.

- **Eye examinations** are recommended at regular intervals while using Neupro. However, if you notice any problems with your sight in-between examinations, you should contact your doctor immediately.
- If you have serious **liver problems**, your doctor may need to adjust the dose. If during treatment your liver problems get worse, you should contact your doctor as soon as possible.
- If you **feel very drowsy** or find that you **fall asleep suddenly**, please contact your doctor (see also below in this section, under '**Driving and using machines**').
- Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormal high sex drive or preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.
- Neupro may cause **abnormal thinking and behaviour**. This abnormal thinking and behaviour can consist of one or more of a variety of manifestations including abnormal thoughts about reality, delusions, hallucinations (seeing or hearing things that are not real), confusion, disorientation, aggressive behaviour, agitation, and delirium. If you notice such effects, please contact your doctor.
- Neupro can cause **skin reactions**, such as reddening and itching. They are usually mild or moderate, and only affect the area of skin the patch has been on. The reactions normally disappear after a few hours when you remove the patch. If you have a skin reaction which lasts for more than a few days, is severe, or spreads outside the area of skin that was 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. To help avoid the skin reactions, you should put the patch on a different area of skin every day, and only use the same area again after 14 days.
- You may experience that symptoms of **Restless Legs Syndrome** start earlier than usual, be more intense and involve other limbs.

Children and adolescents

Neupro should **not be used by children** because its safety and efficacy has not been established in children.

Other medicines and Neupro

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should not take the following medicines while using Neupro, because they may decrease its effect: anti-psychotics (used to treat certain mental conditions) or metoclopramide (used to treat nausea and vomiting).

Please ask your doctor whether it is safe for you to:

- take medicines that lower blood pressure. Neupro may decrease blood pressure when you stand up; this effect may worsen by the medicine used to lower blood pressure.
- take sedating medicines (for example benzodiazepines, medicines used to treat mental conditions or depression) while you are using Neupro.

Neupro with food, drink and alcohol

Because rotigotine enters your bloodstream through your skin, food or drink does not affect the way this medicine works. You should discuss with your doctor if it is safe for you to drink alcohol while using Neupro.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not use Neupro if you are pregnant, as the effects of rotigotine on pregnancy and the unborn baby are not known. Breast-feeding is not recommended during treatment with Neupro. Rotigotine may pass into your breast milk and affect your baby and is also likely to reduce the amount of milk you produce.

Driving and using machines

Neupro may make you feel very drowsy, and you may fall asleep very suddenly. If this affects you, you should not drive or take part in activities where not being alert may put you or others at risk of serious injury, for example, using machines.

In isolated cases people have fallen asleep while driving and this has caused accidents.

Neupro contains sodium metabisulphite (E223)

Sodium metabisulphite (E223) may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How to use Neupro

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For reaching the needed doses, different patches of Neupro are available, each releasing a different amount of the active substance per day: 1 mg/24 h, 2 mg/24 h and 3 mg/24 h.

You will start by using one Neupro 1 mg/24 h patch daily. If necessary, this daily dose may be increased by 1 mg, on a weekly basis, until reaching the right (maintenance) dose for you. This is when you and your doctor agree that the symptoms are adequately controlled and the side effects of the medicines are acceptable.

The maximum dose is 3 mg per day.

If you have to stop taking this medicine, see Section 3, '**If you stop using Neupro**'.

Follow these instructions when using Neupro:

Neupro is for transdermal use, a patch to be applied to the skin.

You should stick a new Neupro patch onto the skin **once a day**. Leave the patch on your skin for 24 hours, then remove it and apply a new one. Make sure that you take the old patch off before applying a new one; place the new patch on a different area of skin.

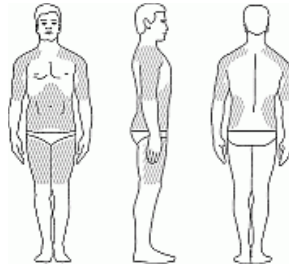
You should **change your patch** at around the **same time every day**.

Do not cut the Neupro patches into pieces.

Where to stick the patch

Put the sticky side of the patch onto clean, dry, healthy skin on the following areas, as indicated by the grey areas in the picture:

- 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; on your upper body one day, then on your lower body.
- Do not stick Neupro on the same area of skin twice within 14 days.
- Do not stick the patch on broken or damaged skin or on skin that is red or irritated.

If you still get problems with your skin because of the patch, please see in Section 4 ‘Possible side effects’ the details about what you should do.

To prevent the patch becoming loose or falling off

- Do not put the patch in an area where it can be rubbed by tight clothing.
- 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.
- If you need to stick the patch to a hairy area of skin, you must shave the area at least 3 days before sticking the patch there.

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.

NOTE

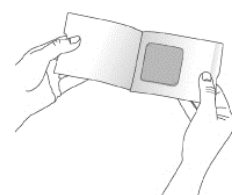
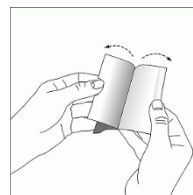
- Bathing, showering and exercising should not affect how Neupro works. Nevertheless, check that the patch has not fallen off afterwards.
- You should avoid external heat (for example excessive sunlight, saunas, hot baths heating pads or hot-water bottles) on the area of the patch.
- If the patch has irritated your skin, you should keep that area protected from direct sunlight, as it may cause changes in the colour of the skin.

How to use the patch

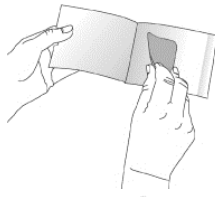
Each patch is packed in a separate sachet. You should stick Neupro onto your skin as soon as you have opened the sachet and removed the release liner.

1.

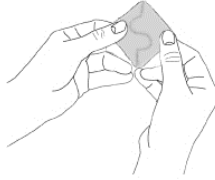
To open the sachet, hold the two sides of the sachet. Peel apart the foil and open the sachet.



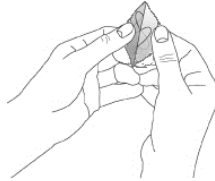
- 2.**
Take the patch out of the sachet.



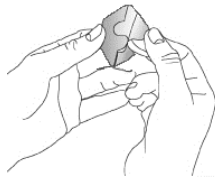
- 3.**
The sticky side of the patch is covered by a transparent release liner. Hold the patch in both hands with the release liner facing you.



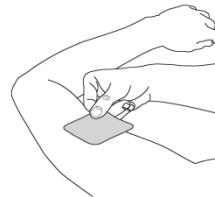
- 4.**
Bend the patch in half so that the S-shaped break in the liner opens.



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



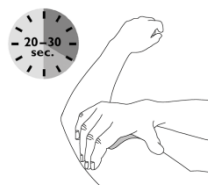
- 6.**
Hold the other half of the rigid release liner and put the sticky surface of the patch onto your skin. Press the sticky side of the patch firmly into place.



- 7.**
Fold back the other half of the patch and remove the other side of the release liner.



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



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

How to remove a used 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 as these may irritate your skin.

Choose a new area of skin where you will apply a new patch, then follow the instructions above.

If you use more Neupro than you should

Using higher doses of Neupro than your doctor has prescribed may cause side effects such as nausea (feeling sick), vomiting, low blood pressure, hallucinations (seeing or hearing things that are not real), confusion, extreme sleepiness, involuntary movements and convulsions.

If you have used more patches than your doctor told you to, contact your doctor or hospital for advice immediately, and follow their advice on removal of patches.

If you have forgotten to change the patch at the usual time

If you have forgotten to change the patch at your usual time, change it as soon as you remember: remove the old patch and use a new one. If you have forgotten to stick on a new patch after removing the old one, use a new patch as soon as you remember.

In both cases, 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 stop using Neupro

Do not stop using Neupro suddenly without talking to your doctor. A sudden stop could cause you to develop a medical condition called neuroleptic malignant syndrome which may represent a major health risk. The symptoms include: akinesia (loss of muscle movement), rigid muscles, fever, unstable blood pressure, tachycardia (increased heart rate), confusion, depressed level of consciousness (e.g. coma).

Your daily dose of Neupro should be reduced gradually

- by 1 mg every other day - if you use Neupro **for Restless Legs Syndrome**

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

4. Possible side effects

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

You may experience **nausea** (feeling sick) and **vomiting at the beginning of treatment**. These effects are usually mild or moderate and only last for a short time. You should contact your doctor if they last for a long time or if you worry about them.

Skin problems caused by the patch

You may get skin reactions from the patch such as redness, itching. They are usually mild or moderate and only affect the area of skin the patch has been on. The reactions normally disappear after a few hours when you remove the patch.

If you have a skin reaction that lasts longer than a few days, is severe, or spreads outside the area of skin that was covered by the patch, you should contact your doctor.

You may experience the following side effects:

Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:

- strong impulse to gamble excessively despite serious personal or family consequences
- altered or increased sexual interest and behaviour of significant concern to you or others, for example, an increased sex drive
- uncontrolled excessive shopping or spending

- binge eating (eating large amounts of food in a short period of time) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)

Tell your doctor if you experience any of these behaviours; he/she will discuss ways of managing or reducing symptoms.

You may experience swelling of the face, tongue and/or lips. If these symptoms develop, please contact your doctor.

If you are using Neupro for Restless Legs Syndrome the following side effects may occur:

Very common side effects: may affect more than 1 in 10 people

- feeling sick (nausea)
- skin irritations under the patch such as redness and itching
- weakness (fatigue)
- headache

Common side effects: may affect up to 1 in 10 people

- vomiting, heartburn
- irritability
- allergic reaction
- sleepiness, falling asleep suddenly without warning, difficulty in sleeping, sleep problems, having unusual dreams
- increased sex drive
- itching
- high blood pressure
- inability to resist the impulse to perform an action that is harmful involving excessive gambling, repetitive meaningless actions, binge eating, compulsive eating and compulsive shopping
- swelling of legs and feet

Uncommon side effects: may affect up to 1 in 100 people

- feeling dizzy when standing up because of a fall in blood pressure
- agitation

Rare side effects: may affect up to 1 in 1,000 people

- aggressive behaviour/aggression
- disorientation

Not known: cannot be estimated from the available data

- excessive use of Neupro (craving for large doses of dopaminergic medicines in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome)
- seeing or hearing things that are not real (hallucinations)
- nightmare
- paranoia
- confusion
- psychotic disorders
- delusion
- delirium
- dizziness
- loss of consciousness, involuntary movements (dyskinesia)
- involuntary muscle spasms (convulsion)
- blurred vision
- visual disturbances such as seeing colours or lights
- vertigo (sensation of whirling motion)

- feeling of heartbeat (palpitation)
- abnormal heart rhythm
- low blood pressure
- hiccups
- constipation, dry mouth
- stomach discomfort and pain
- redness, increased sweating
- generalised itching, skin irritation
- generalised rash
- unable to achieve or maintain an erection
- weight loss, weight increase
- increased or abnormal liver function test results
- increased heart rate
- increased levels of creatine phosphokinase (CPK) in blood in Japanese patients (CPK is an enzyme found mainly in skeletal muscles)
- falling.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Neupro

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton.

Do not store above 30°C.

What to do with the used and unused patches

Used patches still contain active substance, 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 throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Neupro contains

- The active substance is rotigotine.
Each patch releases 3 mg of rotigotine per 24 hours. Each patch of 15 cm² contains 6.75 mg of rotigotine.
- The other ingredients are poly(dimethylsiloxane, trimethylsilyl silicate)-copolymerisate, povidoneK90, sodium metabisulphite (E223), ascorbyl palmitate (E304) and DL- α -tocopherol (E307).
Backing layer: Polyester film, siliconized, aluminized, colour coated with a pigment (titanium dioxide (E171), pigment yellow 95, pigment red 166) layer and imprinted (pigment red 144, pigment yellow 95, pigment black 7).
Release liner: Transparent fluoropolymer coated polyester film.

What Neupro looks like and contents of the pack

Neupro is a transdermal patch. It is thin and has three layers. It is square-shaped with rounded edges. The outside is tan-coloured and is imprinted with Neupro 3 mg/24 h.

Neupro is available in the following pack-sizes:

Cartons containing 7, 28, 30 or 84 (multipack containing 2 packs of 42) patches, which are individually sealed in sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

UCB Manufacturing Ireland Ltd.
Shannon, Industrial Estate,
Co. Clare, Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Lietuva

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Luxembourg/Luxemburg

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.