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URL of this page: <https://medlineplus.gov/druginfo/meds/a607059.html>

Rotigotine Transdermal Patch

pronounced as (roe tig' oh teen)

Why is this medication prescribed?

Rotigotine transdermal patches are used to treat the signs and symptoms of Parkinson's disease (PD; a disorder of the nervous system that causes difficulties with movement, muscle control, and balance) including shaking of parts of the body, stiffness, slowed movements, and problems with balance. Rotigotine transdermal patches are also used to treat restless legs syndrome (RLS or Ekbom syndrome; a condition that causes discomfort in the legs and a strong urge to move the legs, especially at night and when sitting or lying down). Rotigotine is in a class of medications called dopamine agonists. It works by acting in place of dopamine, a natural substance produced in the brain that is needed to control movement.

How should this medicine be used?

Transdermal rotigotine comes as a patch to apply to the skin. It is usually applied once a day. Apply the rotigotine patch at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Use rotigotine exactly as directed.

Your doctor will probably start you on a low dose of rotigotine and gradually increase your dose, not more often than once a week.

Rotigotine controls the symptoms of Parkinson's disease and restless legs syndrome but does not cure them. It may take several weeks before you feel the full benefit of rotigotine. Continue to use rotigotine patches even if you feel well. Do not stop using rotigotine transdermal patches without talking to your doctor. If you suddenly stop using rotigotine patches, you may experience fever, muscle stiffness, change in

consciousness, or other symptoms. Your doctor will probably decrease your dose gradually.

Apply the patch to an area on the stomach, thigh, hip, flank (side of the body between the ribs and pelvis), shoulder, or upper arm. The area of skin should be clean, dry and healthy. Do not apply the patch to skin that is oily, red, irritated, or injured. Do not use creams, lotions, ointments, oils, or powders on the area of skin where the patch will be placed. Do not apply the patch to skin folds and areas of skin that could be under a waistband or rubbed by tight clothing. If the patch is to be applied to a hairy area, shave the area at least 3 days before applying the patch. Select a different area of skin each day such as changing from the right side to the left side or by moving from the upper body to the lower body. Do not apply the rotigotine patch to the same area of skin more often than once every 14 days.

While you are wearing the patch, keep the area away from other sources of heat such as heating pads, electric blankets and heated waterbeds; or direct sunlight. Do not take a hot bath or use a sauna.

Be careful to not dislodge the patch during bathing or physical activity. If the edges of the patch lift, use a bandage tape to re-secure it to the skin. If the patch falls off, apply a new patch to a different place on your skin for the rest of the day. The following day, remove that patch and apply a new patch at the usual time.

If the area of skin that was covered by the patch becomes irritated or develops a rash, do not expose this area to direct sunlight until the skin heals. Exposure of this area to sun could cause changes in your skin color.

Do not cut or damage a rotigotine patch.

To apply the patch, follow these steps:

1. Hold the two sides of the pouch and pull apart.
2. Remove patch from the pouch. Apply the patch right away after removing it from the protective pouch.
3. Hold the patch with both hands, with the protective liner on top.
4. Bend the edges of the patch away from you so that the S-shaped cut in the liner opens.
5. Peel off one half of the protective liner. Do not touch the sticky surface because the

medicine could come off on your fingers.

6. Apply the sticky half of the patch to a clean area of skin and remove the remaining liner.
7. Press the patch firmly with the palm of your hand for 30 seconds. Go around the edges with your fingers to press them onto the skin. Make sure that the patch is flat against the skin (there should be no bumps or folds in the patch).
8. After applying the new patch, be sure to remove the patch from the previous day. Use your fingers to peel it off slowly. Fold the patch in half with and press firmly to seal it shut. Dispose of it safely, so that it is out of the reach of children and pets.
9. If there is any adhesive left on the skin, gently wash the area with warm water and mild soap or gently rub the area with baby or mineral oil to remove it.
10. Wash your hands with soap and water. Do not touch your eyes or any objects until you have washed your hands.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using the rotigotine patch,

- tell your doctor and pharmacist if you are allergic to rotigotine, sulfites, or any other medications, or any of the ingredients in rotigotine transdermal patches. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: antidepressants, medications for anxiety, medications for mental illness, medications for seizures, metoclopramide (Reglan), sedatives, sleeping pills, and tranquilizers. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have asthma, high or low blood pressure, mental illness, daytime sleepiness from a sleep disorder or if you have had times that you fell asleep suddenly and without warning during the daytime or heart disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking rotigotine, call your doctor.

- you should know that rotigotine may make you drowsy or may cause you to suddenly fall asleep during your regular daily activities. You might not feel drowsy before you suddenly fall asleep. Do not drive a car or operate machinery at the beginning of your treatment until you know how the medication affects you. If you suddenly fall asleep while you are doing something such as watching television or riding in a car, or if you become very drowsy, call your doctor. Do not drive or operate machinery until you talk to your doctor.
- remember that alcohol can add to the drowsiness caused by this medication. Tell your doctor if you regularly drink alcoholic beverages.
- you should know that rotigotine may cause dizziness, lightheadedness, fainting, or sweating when you get up too quickly from a lying position. This is more common when you first start taking rotigotine or as the dose is being increased. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- you should know that your blood pressure may increase during your treatment with rotigotine. Your doctor will probably monitor your blood pressure during your treatment.
- you should know that transdermal rotigotine can cause burns on your skin if you are having magnetic resonance imaging (MRI; a radiology technique designed to show the images of body structures) or cardioversion (a procedure to normalize the heart rhythm). Tell your doctor that you are using transdermal rotigotine if you are to have either of these procedures.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Apply the missed dose (patch) as soon as you remember it, then apply a new patch at the usual time the next day. Do not apply an extra patch to make up for a missed dose.

What side effects can this medication cause?

Rotigotine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- rash, redness, swelling or itching of the skin that was covered by the patch
- nausea
- vomiting

- constipation
- loss of appetite
- drowsiness
- difficulty falling asleep or staying asleep
- abnormal dreams
- dizziness or feeling that you or the room is moving
- headache
- fainting
- weight gain
- swelling of the hands, feet, ankles, or lower legs
- increased sweating
- dry mouth
- loss of energy
- joint pain
- abnormal vision
- sudden movements of legs or worsening of symptoms of PD or RLS
- rapid or irregular heartbeat

Some side effects can be serious. If you experience any of these symptoms or those listed in the SPECIAL PRECAUTIONS section, call your doctor immediately:

- difficulty breathing or swallowing
- hives
- rash
- itching
- seeing things or hearing voices that do not exist (hallucinating)

Some people who took medications such as rotigotine to treat Parkinson's disease developed gambling problems, increased sexual urges, or other intense urges. There is not enough information to tell whether the people developed these problems because

they took the medication or for other reasons. Call your doctor if you have an urge to gamble, sexual urges or other urges that are difficult to control. Tell your family members about these risks so that they can call the doctor even if you do not realize that these urges have become a problem.

People who have Parkinson's disease may have a greater risk of developing melanoma (a type of skin cancer) than people who do not have Parkinson's disease. There is not enough information to tell whether medications used to treat Parkinson's disease such as rotigotine increase the risk of developing skin cancer. You should have regular skin examinations to check for melanoma while you are taking rotigotine even if you do not have Parkinson's disease. Talk to your doctor about the risk of taking rotigotine.

Rotigotine may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the original pouch it came in, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

If someone applies extra rotigotine patches, remove the patches. Then call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not

breathing, call local emergency services at 911.

Symptoms of overdose may include:

- nausea
- vomiting
- fainting
- dizziness
- lightheadedness
- movements that are difficult to control
- seeing things or hearing voices that do not exist (hallucinating)
- confusion
- seizures

What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else use your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Neupro ®

Last Revised – 08/15/2016



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Page last updated: 23 August 2016