

PATIENT INFORMATION
NEUPRO® [NU pro]
(rotigotine transdermal system)

If you have Parkinson's disease, read this side. If you have Restless Legs Syndrome (also known as Willis-Ekbom disease), read the other side.

Rx Only

IMPORTANT: NEUPRO is for use on the skin only.

What is NEUPRO?

NEUPRO is a prescription medicine used to treat Parkinson's disease (PD). NEUPRO is a patch worn on the skin.

It is not known if NEUPRO is safe and effective in children.

Who should not use NEUPRO?

Do not use NEUPRO if you are allergic to rotigotine or any of the ingredients in NEUPRO. See the end of this leaflet for a complete list of ingredients in NEUPRO.

What should I tell my doctor before using NEUPRO?

Before you start using NEUPRO, tell your doctor if you:

- have breathing problems including asthma.
- have daytime sleepiness from a sleep disorder or have unexpected or unpredictable sleepiness or periods of sleep.
- have mental problems such as schizophrenia, bipolar disorder, or psychosis.
- feel dizzy, nauseated, sweaty, or faint when you stand up from sitting or lying down.
- drink alcoholic beverages. This may increase your chances of becoming drowsy or sleepy while using NEUPRO.
- have high or low blood pressure.
- have or have had heart problems.
- are pregnant or plan to become pregnant. It is not known if NEUPRO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if NEUPRO passes into your breastmilk. You and your doctor should decide if you will use NEUPRO or breast feed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

NEUPRO and other medicines may affect each other causing side effects. NEUPRO may affect the way other medicines work, and other medicines may affect how NEUPRO works.

Especially tell your doctor if you take other medicines that can make you sleepy such as sleep medicines, antidepressants, or antipsychotics.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use NEUPRO for Parkinson's disease?

- Read the Instructions for Use at the end of this leaflet for specific information about the right way to apply the NEUPRO patch.
- Use NEUPRO exactly as your doctor tells you to use it.
- NEUPRO comes in 4 different size (dose) patches for Parkinson's disease. Your doctor should start you on a low dose of NEUPRO. Your doctor will change the dose weekly until you are taking the right amount of medicine to control your symptoms. It may take several weeks before you reach the dose that controls your symptoms best.
- Apply NEUPRO 1 time each day at the same time each day.
- You may bathe, shower, or swim while wearing a NEUPRO patch. Water may loosen your NEUPRO patch.
- If the edges of the patch lift, you may tape them down with bandaging tape.
- If your NEUPRO patch falls off, apply a new NEUPRO patch for the rest of the day. The next day, apply a new patch at your regular time.
- If you miss a dose or forget to change your NEUPRO patch, apply a new NEUPRO patch as soon as you remember. Replace the NEUPRO patch at your normal time the next day.
- Talk to your doctor often about your condition. **Do not** stop or change your treatment with NEUPRO without talking to your doctor.

What should I avoid while using NEUPRO?

- **Do not** drive, operate machinery, or do other dangerous activities until you know how NEUPRO affects you.
- Avoid exposing the site where you have applied your NEUPRO patch to heating pads, electric blankets, heat lamps, saunas, hot tubs, heated water beds, and direct sunlight. Too much medicine could be absorbed into your body.
- **Do not** use NEUPRO during certain medical procedures called magnetic resonance imaging (MRI) or cardioversion. Using NEUPRO during these procedures could cause a burn to the site where you applied your NEUPRO patch.
- Avoid direct sunlight if you get a skin rash or irritation from NEUPRO until your skin heals. Sun exposure could lead to skin color changes.

What are the possible side effects of NEUPRO?

NEUPRO can cause serious side effects, including:

- **severe allergic reactions.** NEUPRO contains a sulfite called sodium metabisulfite. Sulfites can cause severe allergic reactions that are life threatening to some people who are sensitive to sulfites. An allergy to sulfites is not the same as an allergy to sulfa. People with asthma are more likely to be allergic to sulfites. Remove your NEUPRO patch right away and call your doctor if you have swelling of the lips or tongue, chest pain, trouble breathing or swallowing.
- **falling asleep during normal activities.** You may fall asleep while doing normal activities such as driving a car, doing physical tasks, or using hazardous machinery while taking NEUPRO. You may suddenly fall asleep without being drowsy or without warning. This may result in having accidents. Your chances of falling asleep while doing normal activities while using NEUPRO are greater if you take other medicines that cause drowsiness. Tell your doctor right away if this happens. Before starting NEUPRO, be sure to tell your doctor if you take any medicines that make you drowsy.
- **hallucinations and other psychosis.** NEUPRO can cause or worsen psychotic symptoms including hallucinations (seeing or hearing things that are not real), confusion, excessive suspicion, aggressive behavior, agitation, delusional beliefs (believing things that are not real), and disorganized thinking. The chances of having hallucinations or these other psychotic-like changes are higher in people with Parkinson's disease who are elderly, taking NEUPRO, or taking higher doses of NEUPRO. If you have hallucinations or any of these other psychotic-like changes, talk with your doctor.

- **changes in blood pressure.** NEUPRO can decrease or increase your blood pressure. Lowering of your blood pressure is of special concern. If you faint or feel dizzy, nauseated, or sweaty when you stand up from sitting or lying down, this may mean that your blood pressure is decreased. If you notice this, you should contact your doctor. Also, when changing position from lying down or sitting to standing up, you should do it carefully and slowly. Lowering of your blood pressure can happen, especially when you start taking NEUPRO or when your dose is increased.
- **fainting.** Fainting can occur, and sometimes your heart rate may be decreased. This can happen especially when you start using NEUPRO or your dose is increased. Tell your doctor if you faint or feel dizzy.
- **unusual urges.** Some patients using NEUPRO get urges to behave in a way unusual for them. Examples of this are an unusual urge to gamble, strong urges to spend money, binge eating, or increased sexual urges and behaviors. If you notice or your family notices that you are developing any unusual behaviors, talk to your doctor.
- **changes in heart rate.** NEUPRO can increase your heart rate.
- **increased weight and fluid retention** can occur in patients using NEUPRO. NEUPRO can cause your body to keep extra fluid which leads to swelling and weight gain. Tell your doctor if you have swelling or fluid retention, especially in the ankles or legs, or have an unusually fast increase in weight.
- **uncontrolled, sudden movements.** NEUPRO may cause uncontrolled, sudden movements or make such movements you already have worse or more frequent. Tell your doctor if this happens. The doses of your anti-Parkinson's medicine may need to be changed.
- **skin site reactions.** Skin reactions may occur at the site where you apply NEUPRO. Tell your doctor if you get a rash, redness, swelling, or itching that will not go away at the skin site where you have applied NEUPRO.
- **skin cancer.** Some people with Parkinson's disease may have an increased chance of getting a skin cancer called melanoma. People with Parkinson's disease should have a doctor check their skin for skin cancer regularly.

The most common side effects of NEUPRO for Parkinson's disease are nausea, vomiting, sleepiness, application site reactions, dizziness, loss of appetite, difficulty falling asleep and staying asleep, increased sweating, vision problems, leg swelling, and uncontrolled, sudden movements of arms or legs.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of NEUPRO. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NEUPRO?

- Store NEUPRO at 68°F to 77°F (20°C to 25°C).
- Store NEUPRO in its original sealed pouch until use. **Do not** store NEUPRO outside of the pouch.

Keep NEUPRO and all medicines out of reach of children and away from pets.

General information about the safe and effective use of NEUPRO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use NEUPRO for a condition for which it was not prescribed. Do not give NEUPRO to other people even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about NEUPRO. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about NEUPRO that was written for health professionals.

For more information, go to www.neupro.com or call 1-844-599-2273.

What are the ingredients in NEUPRO?

Active ingredient: rotigotine

Inactive ingredients: ascorbyl palmitate, povidone, silicone adhesive, sodium metabisulfite, and dl-alpha-tocopherol.

INSTRUCTIONS FOR USE NEUPRO® [NU pro] (rotigotine transdermal system)

When to apply NEUPRO:

Each NEUPRO patch is sealed in a pouch that protects it until you are ready to apply it. **See Figure A.**



Figure A

- NEUPRO should be applied right away after removing it from the protective pouch. **Do not** damage or cut your NEUPRO patch into smaller pieces.
- Choose the time of day or night that works best for you to apply your NEUPRO patch. Apply your NEUPRO patch at the same time each day.
- Wear your NEUPRO patch for 24 hours.
- After 24 hours, remove your NEUPRO patch and apply a new one right away to a different area of your skin.

Where to apply NEUPRO:

- Choose an area of clean, dry, and healthy skin on the stomach, thigh, hip, side of the body between the ribs and the pelvis (flank), shoulder, or upper arm. **See Figure B.**

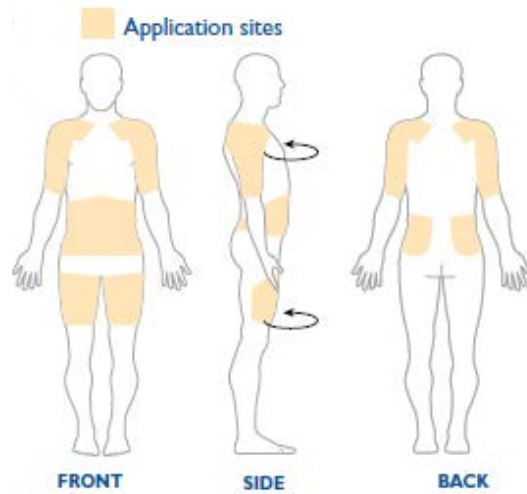


Figure B

- Apply your NEUPRO patch to a different place on your skin each day, for example, from the right side to the left side and from the upper body to the lower body. Your NEUPRO patch should not be applied to the same area of your skin more than 1 time every 14 days. Apply NEUPRO to a different area of skin (*only one of the shaded areas in Figure B*) each day to reduce the chance of getting skin irritation.
- If you need to apply your NEUPRO patch to a hairy area, the area should be shaved at least 3 days before applying the patch.
- Avoid applying your NEUPRO patch to areas where it could be rubbed by tight clothing or under a waistband.
- Avoid applying your NEUPRO patch on skin folds.
- **Do not** apply your NEUPRO patch to skin that is red, irritated, or injured.
- Avoid applying creams, lotions, ointments, oils, and powders to the skin area where your NEUPRO patch will be placed.

How to apply NEUPRO:

Step 1. Grasp the two sides of the pouch and pull apart. **See Figures C and D.**

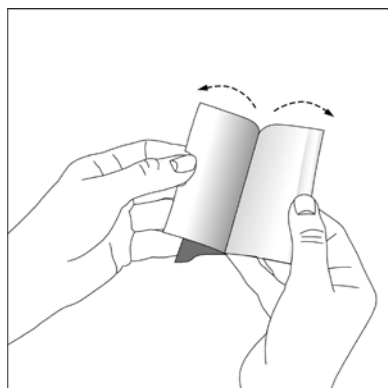


Figure C

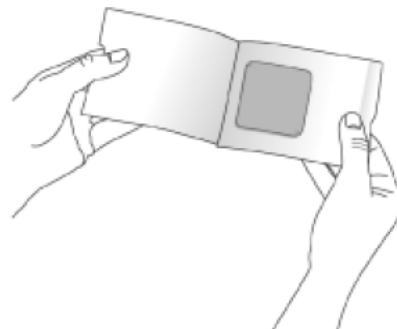


Figure D

Step 2. Remove your NEUPRO patch from the pouch. **See Figure E.**

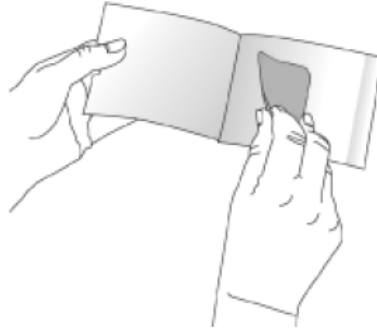


Figure E

Step 3. Hold your NEUPRO patch with both hands, with the protective liner on top. **See Figure F.**

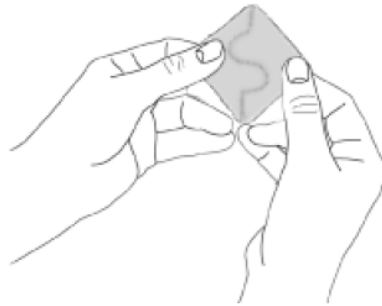


Figure F

Step 4. Bend the edges of your NEUPRO patch away from you so that the S-shaped cut in the liner opens up. **See Figure G.**

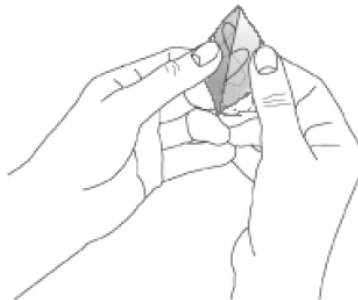


Figure G

Step 5. Peel off one half of the protective liner. **Do not** touch the sticky surface of your NEUPRO patch because the medicine could come off on your fingers. **See Figure H.**

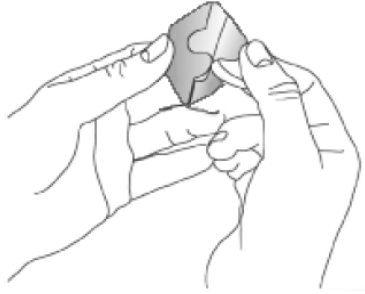


Figure H

Step 6. Apply the sticky half of your NEUPRO patch to a clean area of your skin and remove the remaining liner. **See Figures I and J.**

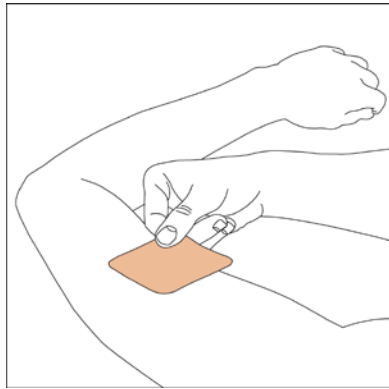


Figure I

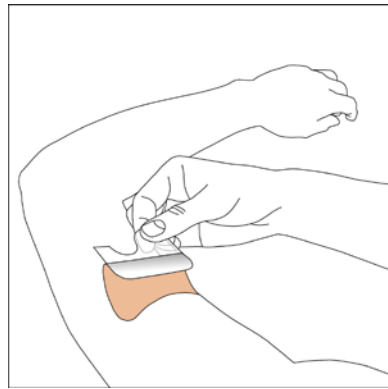


Figure J

Step 7. Press your NEUPRO patch firmly with the palm of your hand for **30** seconds to make sure there is good contact with your skin, especially around the edges. The warmth of your hand helps the adhesive on the patch to stick to your skin. Make sure that your NEUPRO patch is flat against your skin. There should be no bumps or folds in your NEUPRO patch. **See Figure K.**

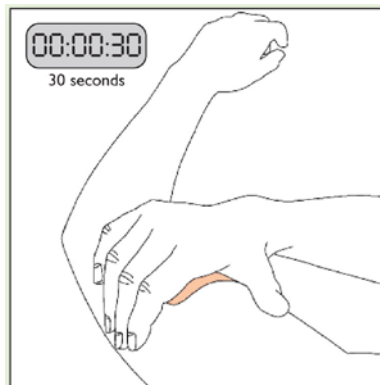


Figure K

Step 8. Wash your hands with soap and water right after handling your NEUPRO patch to remove any medicine that may have gotten on them. **Do not** touch your eyes until after you have washed your hands.

How to remove NEUPRO:

- Slowly and carefully peel off your used NEUPRO patch. Carefully fold it in half (sticky sides together) and throw away the folded patch so that children and pets cannot reach it. Your NEUPRO patch still contains some medicine and could harm a child or pet.
- Gently wash the area with warm water and mild soap to remove any sticky material (adhesive) that stays on your skin.
- Baby or mineral oil may also be used to remove any adhesive. Avoid using alcohol or other solvents, such as nail polish remover. They may cause your skin to become irritated.
- Wash your hands with soap and water.
- You may see mild redness at the site when a patch is removed like when you remove an adhesive bandage. This redness should go away over time. If irritation or itchiness continues, tell your doctor.

This Patient Package Insert and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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PATIENT INFORMATION
NEUPRO® [NU pro]
(rotigotine transdermal system)

If you have Restless Legs Syndrome (also known as Willis-Ekbom disease), read this side. If you have Parkinson's disease, read the other side.

Rx Only

IMPORTANT: NEUPRO is for use on the skin only.

What is NEUPRO?

NEUPRO is a prescription medicine used to treat moderate-to-severe primary Restless Legs Syndrome (RLS). NEUPRO is a patch worn on the skin.

It is not known if NEUPRO is safe and effective in children.

Who should not use NEUPRO?

Do not use NEUPRO if you are allergic to rotigotine or any of the ingredients in NEUPRO. See the end of this leaflet for a complete list of ingredients in NEUPRO.

What should I tell my doctor before using NEUPRO?

Before you start using, NEUPRO tell your doctor if you:

- have breathing problems including asthma.
- have daytime sleepiness from a sleep disorder or have unexpected or unpredictable sleepiness or periods of sleep.
- have mental problems such as schizophrenia, bipolar disorder, or psychosis.
- feel dizzy, nauseated, sweaty, or faint when you stand up from sitting or lying down.
- drink alcoholic beverages. This may increase your chances of becoming drowsy or sleepy while using NEUPRO.
- have high or low blood pressure.
- have or have had heart problems.
- are pregnant or plan to become pregnant. It is not known if NEUPRO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if NEUPRO passes into your breastmilk. You and your doctor should decide if you will use NEUPRO or breast feed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

NEUPRO and other medicines may affect each other causing side effects. NEUPRO may affect the way other medicines work, and other medicines may affect how NEUPRO works.

Especially tell your doctor if you take other medicines that can make you sleepy such as sleep medicines, antidepressants, or antipsychotics.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use NEUPRO for RLS?

- Read the Instructions for Use at the end of this leaflet for specific information about the right way to apply the NEUPRO patch.
- Use NEUPRO exactly as your doctor tells you to use it.

- NEUPRO comes in 3 different size (dose) patches for RLS. Your doctor should start you on the lowest dose of NEUPRO. Your doctor may change the dose weekly until you are taking the right amount of medicine to control your symptoms. It may take several weeks before you reach the dose that controls your symptoms best.
- Apply NEUPRO 1 time each day at the same time each day.
- You may bathe, shower, or swim while wearing a NEUPRO patch. Water may loosen your NEUPRO patch.
- If the edges of the patch lift, you may tape them down with bandaging tape.
- If your NEUPRO patch falls off, apply a new NEUPRO patch for the rest of the day. The next day, apply a new patch at your regular time.
- If you miss a dose or forget to change your NEUPRO patch, apply a new NEUPRO patch as soon as you remember. Replace the NEUPRO patch at your normal time the next day.
- Talk to your doctor often about your condition. **Do not** stop or change your treatment with NEUPRO without talking to your doctor.

What should I avoid while using NEUPRO?

- **Do not** drive, operate machinery, or do other dangerous activities until you know how NEUPRO affects you.
- Avoid exposing the site where you have applied your NEUPRO patch to heating pads, electric blankets, heat lamps, saunas, hot tubs, heated water beds, and direct sunlight. Too much medicine could be absorbed into your body.
- **Do not** use NEUPRO during certain medical procedures called magnetic resonance imaging (MRI) or cardioversion. Using NEUPRO during these procedures could cause a burn to the site where you applied your NEUPRO patch.
- Avoid direct sunlight if you get a skin rash or irritation from NEUPRO until your skin heals. Sun exposure could lead to skin color changes.

What are the possible side effects of NEUPRO?

NEUPRO can cause serious side effects, including:

- **severe allergic reactions.** NEUPRO contains a sulfite called sodium metabisulfite. Sulfites can cause severe allergic reactions that are life threatening to some people who are sensitive to sulfites. An allergy to sulfites is not the same as an allergy to sulfa. People with asthma are more likely to be allergic to sulfites. Remove your NEUPRO patch right away and call your doctor if you have swelling of the lips or tongue, chest pain, trouble breathing or swallowing.
- **falling asleep during normal activities.** You may fall asleep while doing normal activities such as driving a car, doing physical tasks, or using hazardous machinery while taking NEUPRO. You may suddenly fall asleep without being drowsy or without warning. This may result in having accidents. Your chances of falling asleep while doing normal activities while using NEUPRO are greater if you take other medicines that cause drowsiness. Tell your doctor right away if this happens. Before starting NEUPRO, be sure to tell your doctor if you take any medicines that make you drowsy.
- **changes in blood pressure.** NEUPRO can decrease or increase your blood pressure. Lowering of your blood pressure is of special concern. If you faint or feel dizzy, nauseated, or sweaty when you stand up from sitting or lying down, this may mean that your blood pressure is decreased. If you notice this, you should contact your doctor. Also, when changing position from lying down or sitting to standing up, you should do it carefully and slowly. Lowering of your blood pressure can happen, especially when you start taking NEUPRO or when your dose is increased.
- **fainting.** Fainting can occur, and sometimes your heart rate may be decreased. This can happen especially when you start using NEUPRO or your dose is increased. Tell your doctor if you faint or feel dizzy.

- **unusual urges.** Some patients using NEUPRO get urges to behave in a way unusual for them. Examples of this are an unusual urge to gamble, strong urges to spend money, binge eating, or increased sexual urges and behaviors. If you notice or your family notices that you are developing any unusual behaviors, talk to your doctor.
- **changes in heart rate.** NEUPRO can increase your heart rate.
- **skin site reactions.** Skin reactions may occur at the site where you apply NEUPRO. Tell your doctor if you get a rash, redness, swelling, or itching that will not go away at the skin site where you have applied NEUPRO.
- **changes in Restless Legs Syndrome symptoms.** NEUPRO may cause Restless Legs Syndrome symptoms to come back (rebound), or become worse or start earlier in the day.

The most common side effects of NEUPRO for Restless Legs Syndrome (RLS) are application site reactions, nausea, difficulty falling asleep and staying asleep, sleepiness, and headache.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of NEUPRO. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NEUPRO?

- Store NEUPRO at 68°F to 77°F (20°C to 25°C).
- Store NEUPRO in its original sealed pouch until use. **Do not** store NEUPRO outside of the pouch.

Keep NEUPRO and all medicines out of reach of children and away from pets.

General information about the safe and effective use of NEUPRO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use NEUPRO for a condition for which it was not prescribed. Do not give NEUPRO to other people even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about NEUPRO. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about NEUPRO that was written for health professionals.

For more information, go to www.neupro.com or call 1-844-599-2273.

What are the ingredients in NEUPRO?

Active ingredient: rotigotine

Inactive ingredients: ascorbyl palmitate, povidone, silicone adhesive, sodium metabisulfite, and dl-alpha-tocopherol.

INSTRUCTIONS FOR USE NEUPRO® [NU pro] (rotigotine transdermal system)

When to apply NEUPRO:

Each NEUPRO patch is sealed in a pouch that protects it until you are ready to apply it. **See Figure A.**



Figure A

- NEUPRO should be applied right away after removing it from the protective pouch. **Do not** damage or cut your NEUPRO patch into smaller pieces.
- Choose the time of day or night that works best for you to apply your NEUPRO patch. Apply your NEUPRO patch at the same time each day.
- Wear your NEUPRO patch for 24 hours.
- After 24 hours, remove your NEUPRO patch and apply a new one right away to a different area of your skin.

Where to apply NEUPRO:

- Choose an area of clean, dry, and healthy skin on the stomach, thigh, hip, side of the body between the ribs and the pelvis (flank), shoulder, or upper arm. **See Figure B.**

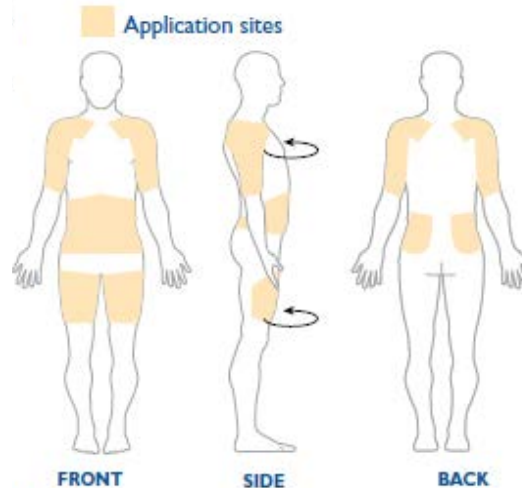


Figure B

- Apply your NEUPRO patch to a different place on your skin each day, for example, from the right side to the left side and from the upper body to the lower body. Your NEUPRO patch should not be applied to the same area of your skin more than 1 time every 14 days. Apply NEUPRO to a different area of skin (*only one of the shaded areas in Figure B*) each day to reduce the chance of getting skin irritation.
- If you need to apply your NEUPRO patch to a hairy area, the area should be shaved at least 3 days before applying the patch.
- Avoid applying your NEUPRO patch to areas where it could be rubbed by tight clothing or under a waistband.

- Avoid applying your NEUPRO patch on skin folds.
- **Do not** apply your NEUPRO patch to skin that is red, irritated, or injured.
- Avoid applying creams, lotions, ointments, oils, and powders to the skin area where your NEUPRO patch will be placed.

How to apply NEUPRO:

Step 1. Grasp the two sides of the pouch and pull apart. **See Figures C and D.**

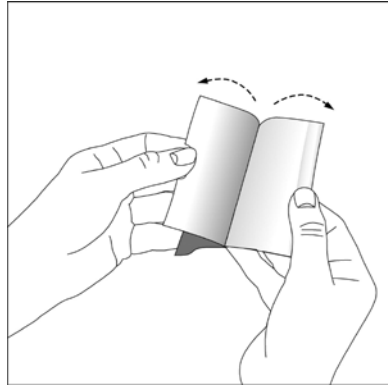


Figure C

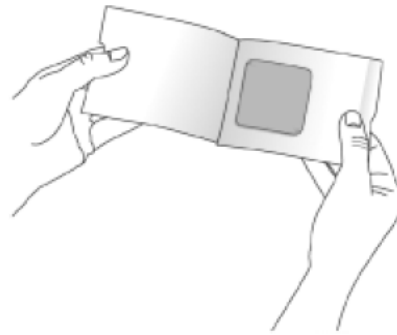


Figure D

Step 2. Remove your NEUPRO patch from the pouch. **See Figure E.**

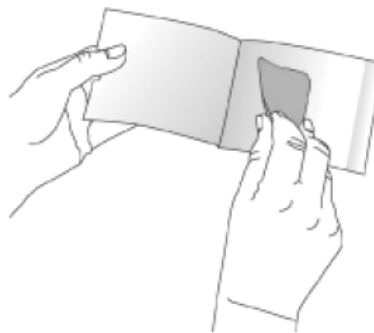


Figure E

Step 3. Hold your NEUPRO patch with both hands, with the protective liner on top. **See Figure F.**

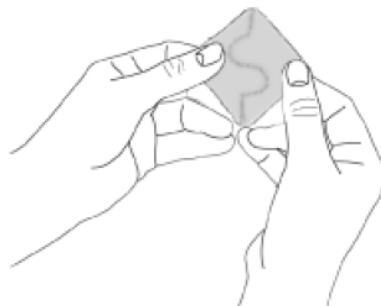


Figure F

Step 4. Bend the edges of your NEUPRO patch away from you so that the S-shaped cut in the liner opens up. **See Figure G.**

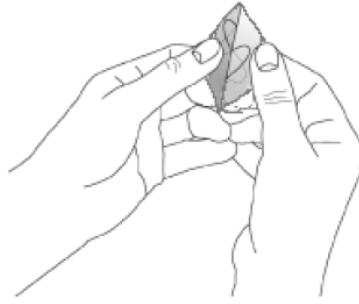


Figure G

Step 5. Peel off one half of the protective liner. **Do not** touch the sticky surface of your NEUPRO patch because the medicine could come off on your fingers. **See Figure H.**

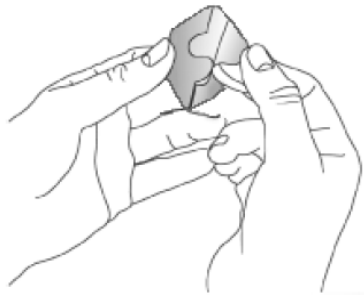


Figure H

Step 6. Apply the sticky half of your NEUPRO patch to a clean area of your skin and remove the remaining liner. **See Figures I and J.**

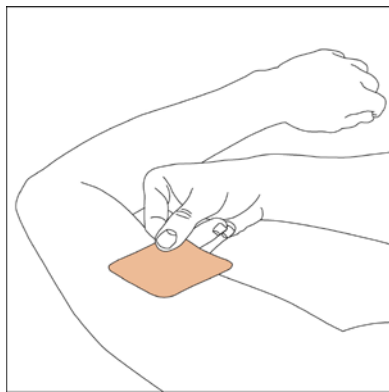


Figure I

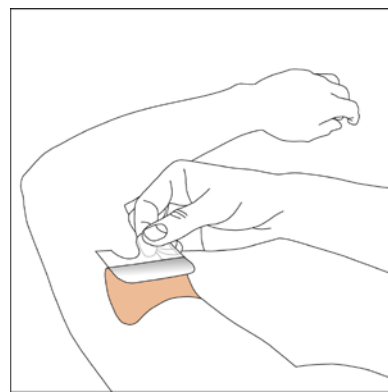


Figure J

Step 7. Press your NEUPRO patch firmly with the palm of your hand for **30** seconds to make sure there is good contact with your skin, especially around the edges. The warmth of your hand helps the adhesive on the patch to stick to your skin. Make sure that your NEUPRO patch is flat against your skin. There should be no bumps or folds in your NEUPRO patch. **See Figure K.**

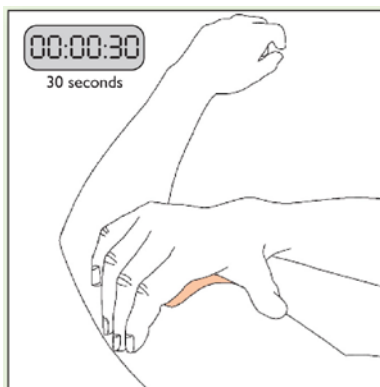


Figure K

Step 8. Wash your hands with soap and water right after handling your NEUPRO patch to remove any medicine that may have gotten on them. **Do not** touch your eyes until after you have washed your hands.

How to remove NEUPRO:

- Slowly and carefully peel off your used NEUPRO patch. Carefully fold it in half (sticky sides together) and throw away the folded patch so that children and pets cannot reach it. Your NEUPRO patch still contains some medicine and could harm a child or pet.
- Gently wash the area with warm water and mild soap to remove any sticky material (adhesive) that stays on your skin.
- Baby or mineral oil may also be used to remove any adhesive. Avoid using alcohol or other solvents, such as nail polish remover. They may cause your skin to become irritated.
- Wash your hands with soap and water.
- You may see mild redness at the site when a patch is removed like when you remove an adhesive bandage. This redness should go away over time. If irritation or itchiness continues, tell your doctor.

This Patient Package Insert and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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