Package Leaflet: Information for the User

ADARTREL (logo) 0.25 mg, 0.5 mg, 2 mg
film-coated tablets
ropinirole (as hydrochloride)

(banner heading at right angles to rest of leaflet)

ADARTREL (logo)
film-coated tablets
ropinirole

Read all of this leaflet carefully before you start taking 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 Adartrel is and what it is used for**
2. **What you need to know before you take Adartrel**
3. **How to take Adartrel**
4. **Possible side effects**
5. **How to store Adartrel**
6. **Contents of the pack and other information**

1. What Adartrel is and what it is used for

The active ingredient in Adartrel is ropinirole, which belongs to a group of medicines called **dopamine agonists**. Dopamine agonists act in a similar way to a natural substance called dopamine, in the brain.

Adartrel is used to treat the symptoms of moderate to severe restless legs syndrome.

Restless legs syndrome (RLS) is also called Ekbom syndrome. People with restless legs syndrome have an irresistible urge to move their legs, and sometimes their arms and other parts of their bodies. Usually, they have unpleasant sensations in their limbs - sometimes described as ‘crawling’ or ‘bubbling’ - which can begin as soon as they sit or lie down, and are relieved only by movement. So they often have problems with sitting still and especially with sleeping.

Adartrel relieves the unpleasant sensations, and so reduces the urge to move the legs and other limbs.

2. What you need to know before you take Adartrel

Do not take Adartrel:

- if you are **allergic** to ropinirole or any of the other ingredients of this medicine (listed in section 6)
- if you have **serious kidney disease**
- if you have **serious liver disease.**

➔ **Tell your doctor** if you think any of these may apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Adartrel:

- if you are **pregnant** or think you may be pregnant
- if you are **breast-feeding**
- if you are **under 18 years old**
- if you have **liver disease**
- if you have a **serious heart complaint**
- if you have a **serious mental health problem**
- if you have experienced any **unusual urges and/or behaviours** (such as **excessive gambling** or **excessive sexual behaviour**)
- if you have an **intolerance to some sugars** (such as lactose monohydrate).

Tell your doctor if you experience symptoms such as **depression, apathy, anxiety, fatigue, sweating or pain** after stopping or reducing your Adartrel treatment **(called dopamine agonist withdrawal syndrome or DAWS)**. If the problems persist more than a few weeks, your doctor may need to adjust your dose.

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 abnormally high sex drive or an increase in sexual thoughts or feelings, or aggressive behaviours. Your doctor may need to adjust or stop your dose.

Tell your doctor if you or your family/carer notices that you are developing episodes of overactivity, elation or irritability (symptoms of mania). These may occur with or without the symptoms of impulse control disorders (see above). Your doctor may need to adjust or stop your dose.

➔ **Talk to your doctor** if any of these may apply to you. If you and your doctor decide that you can take Adartrel, your doctor will probably ask you to have extra check-ups while you are taking it.

Other medicines and Adartrel

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including any herbal medicines or other medicines you obtained without a prescription. Remember to tell your doctor or pharmacist if you begin taking a new medicine while you are taking Adartrel.

Some medicines can affect the way Adartrel works or make it more likely that you will have side effects. Adartrel can also affect how some other medicines work.

These include:
- the **anti-depressant fluvoxamine**
- medication for other **mental health problems**, for example **sulpiride**
- **metoclopramide**, which is used to treat **nausea** and **heartburn**
- **HRT** (hormone replacement therapy)
- the **antibiotics ciprofloxacin** or **enoxacin**
- any other drug which blocks the action of dopamine in the brain.

➔ **Tell your doctor** if you are taking, or have recently taken, any of these.

You will require additional blood tests if you are taking these medicines with Adartrel:

- Vitamin K antagonists (used to reduce blood clotting) such as Warfarin (coumadin).

Pregnancy and breast-feeding

Adartrel is not recommended if you are pregnant, unless your doctor advises that the benefit to you of taking it is greater than the risk to your unborn baby. **Adartrel is not recommended if you are breast-feeding,** as it can affect your milk production.

➔ Talk to your doctor immediately if you are pregnant, if you think you might be pregnant, or if you are planning to become pregnant. Your doctor will also advise you if you are breast-feeding or planning to do so. Your doctor may advise you to stop taking Adartrel.

While you are taking Adartrel

Tell your doctor if you or your family notices that you are developing any **unusual behaviours** (such as an **unusual urge to gamble** or **increased sexual urges and/or behaviours**) while you are taking Adartrel. Your doctor may need to adjust or stop your dose.

- **Driving and using machines**
  Adartrel can make you feel drowsy. In very rare cases, **Adartrel can make people feel extremely sleepy**, and it sometimes makes people fall asleep very suddenly without warning.

  Adartrel can cause hallucinations (seeing, hearing or feeling things that are not there). If affected, do not drive or use machines.

  If you could be affected: **do not drive**, **do not operate machines** and **do not** put yourself in any situation where feeling sleepy or falling asleep could put you (or other people) at risk of serious injury or death. Do not take part in these activities until you are no longer affected.

➔ **Talk to your doctor** if this causes problems for you.

- **Smoking and Adartrel**
  Tell your doctor if you start smoking, or give up smoking, while you are taking Adartrel. Your doctor may need to adjust your dose.

Taking Adartrel with food and drink

If you take Adartrel with food, you may be less likely to feel sick (nauseous) or be sick (vomit). So it may be best to take it with food if you can.

If your symptoms get worse

Some people taking Adartrel find that their RLS symptoms get worse - for example, symptoms may start earlier than usual or be more intense, or affect other previously unaffected limbs, such as the arms or return in the early morning.

➔ **Tell your doctor as soon as possible** if you get any of these symptoms.

Important Information about some of the ingredients in Adartrel

Adartrel tablets contain a small amount of sugar called lactose monohydrate

If you have an intolerance to lactose monohydrate or any other sugars, ask your doctor for advice before you take Adartrel.

Adartrel tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Adartrel

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

Do not give Adartrel to children. Adartrel is not normally prescribed for people under 18.

How much Adartrel will you need to take?

It may take a while to find out what is the best dose of Adartrel for you.

The usual starting dose is 0.25 mg once a day. After two days, your doctor will probably increase your dose to 0.5 mg daily for the rest of the week. Then your doctor may gradually increase your dose over the next three weeks, up to a daily dose of 2 mg.

If a 2 mg daily dose does not improve your RLS symptoms enough, your doctor may gradually increase your dose some more, up to a maximum of 4 mg daily. After you have been taking Adartrel for three months, your doctor may adjust your dose or advise you to stop taking it.

If you feel that the effects of Adartrel are too strong or too weak, talk to your doctor or your pharmacist. **Do not take more tablets than your doctor has recommended**.

Carry on taking Adartrel as your doctor advises, even if you do not feel better. Adartrel may take a few weeks to work for you.

Taking your dose of Adartrel

Take your Adartrel tablet(s) once a day.

Swallow the tablet(s) with a glass of water.

You can take Adartrel with or without food. If you take it with food, you may be less likely to feel sick (nauseous).

Adartrel is usually taken just before bedtime, but you can take it up to 3 hours before you go to bed.

If you take more Adartrel than you should

Contact a doctor or pharmacist immediately. If possible, show them the Adartrel pack.

Someone who has taken an overdose of Adartrel may have any of these symptoms: feeling sick (nausea), being sick (vomiting), dizziness (a spinning sensation), feeling drowsy, mental or physical tiredness, fainting, hallucinations.

If you forget to take Adartrel

Do not take extra tablets or a double dose to make up for a missed dose. Just take your next dose at the usual time.

If you have missed your dose for more than a few days, ask your doctor for advice on how to start taking it again.

If you stop taking Adartrel

Do not stop taking Adartrel without advice.

Take Adartrel for as long as your doctor recommends. Do not stop unless your doctor advises you to.

If you suddenly stop taking Adartrel, your Restless leg syndrome symptoms may quickly get much worse.

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).

If you need to stop taking Adartrel, your doctor will reduce your dose gradually.
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 everyone gets them.

Side effects with this medicine are more likely to happen when you first start taking it, or when your dose has just been increased. They are usually mild, and may become less troublesome after you have taken the dose for a while.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Very common side effects

These may affect **more than 1 in 10** people taking Adartrel:

- feeling sick (nausea)
- being sick (vomiting).

Common side effects

These may affect **up to 1 in 10** people taking Adartrel:

- nervousness
- fainting
- drowsiness

- fatigue (mental or physical tiredness)
- dizziness (a 'spinning' sensation)
- stomach pain
- worsening of RLS (symptoms may start earlier than usual or be more intense, or affect other previously unaffected limbs, such as the arms or return in the early morning)
- swelling of the legs, feet or hands.

Uncommon side effects

These may affect **up to 1 in 100** people taking Adartrel:

- confusion
- hallucinations ('seeing' things that are not really there)
- feeling dizzy or faint, especially when you stand up suddenly (this is caused by a drop in blood pressure)
- low blood pressure (hypotension)
- hiccups

Very rare side effects

A very small number of people taking Adartrel (up to 1 in 10 000) have had:

- changes in liver function, which have shown up in blood tests
- feeling very sleepy during the day (extreme somnolence)
- falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes).

Some patients may have the following side effects (frequency not known: cannot be estimated from the available data)

- allergic reactions such as red, itchy swellings on the skin (hives), swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, rash or intense itching (see section 2)
- other psychotic reactions in addition to hallucinations, such as severe confusion (delirium), irrational ideas (delusions) and irrational suspiciousness (paranoia)
- aggression
- excessive use of Adartrel (craving for large doses of dopaminergic drugs in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome).
- depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS) after stopping or reducing your Adartrel treatment.
- spontaneous penile erection

You may experience the following side effects:

- inability to resist that 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 to others, for example, an increased sexual drive
  - uncontrollable excessive shopping or spending
  - binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than is needed to satisfy your hunger).
- episodes of overactivity, elation or irritability

➔ **Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.**

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Adartrel

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store Adartrel above 25 °C. Store it in its original package in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Adartrel contains

The active substance is ropinirole (as hydrochloride).

Each tablet contains 0.25, 0.5 or 2 mg of ropinirole (as hydrochloride).

The other ingredients are:

- **tablet core**: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate
- **film coat**:
  0.25 mg tablet: hypromellose, macrogol 400, titanium dioxide (E171), polysorbate 80 (E433)
  0.5 mg tablet: hypromellose, macrogol 400, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), indigo carmine aluminium lake (E132)
  2 mg tablet: hypromellose, macrogol 400, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172)

What Adartrel looks like and contents of the pack

Adartrel 0.25 mg is provided as white, pentagonal-shaped film-coated tablets, marked ‘SB’ on one side and ‘4890’ on the other. Each pack contains 12 tablets.
Adartrel 0.5 mg is provided as yellow, pentagonal-shaped film-coated tablets marked ‘SB’ on one side and ‘4891’ on the other. Each pack contains 28 tablets.
Adartrel 2 mg is provided as pink, pentagonal-shaped film-coated tablets marked ‘SB’ on one side and ‘4893’ on the other. Each pack contains 28 tablets.

Marketing Authorisation Holder: GlaxoSmithKline UK Limited, 79 New Oxford Street, London, WC1A 1DG, United Kingdom, **Manufacturer**: Glaxo Wellcome S.A., Avenida de Extremadura 3, 09400 Aranda de Duero, Burgos, Spain

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	**Adartrel 0.25 mg** **Adartrel 0.5 mg** **Adartrel 2 mg**
Reference number	19494/0033

This is a service provided by the Royal National Institute of Blind People.

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