Ropinirole 0.25 mg film-coated tablets Ropinirole 0.5 mg film-coated tablets Ropinirole 2 mg film-coated tablets ropinirole

Package leaflet: Information for the patient 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.
- not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

This medicine has been prescribed for you only. Do

- 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

2. What you need to know before you take Ropinirole

3. How to take Ropinirole 4. Possible side effects

1. What Ropinirole is and what it is used for

5. How to store Ropinirole 6. Contents of the pack and other information

The active substance in Ropinirole Film-Coated

Tablets is ropinirole, which belongs to a group of

- What Ropinirole is and what it is used for
- medicines called dopamine agonists. Dopamine agonists affect the brain in a similar way to a natural substance called dopamine.

People with Parkinson's disease have low levels of

Ropinirole is used to treat:

Parkinson's disease

syndrome.

dopamine in some parts of their brains. Ropinirole has effects similar to those of natural dopamine, so it helps to reduce the symptoms of Parkinson's disease.

Restless legs syndrome (RLS) is also called Ekbom syndrome. People with restless legs syndrome have

their arms and other parts of their bodies. Usually,

an irresistible urge to move their legs, and sometimes

the symptoms of moderate to severe restless legs

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

Ropinirole relieves the unpleasant sensations, and so

reduces the urge to move the legs and other limbs.

Ropinirole Do not take Ropinirole

allergic to ropinirole or any of the other ingredients

allergic to ropinirole, soya or peanut or to any of the

What you need to know before you take

Ropinirole 0.25 mg film-coated tablets: if you are

sleeping.

of this medicine (listed in section 6). Ropinirole 0.5/2 mg film-coated tablets: if you are

other ingredients of this medicine (listed in section 6) if you have serious kidney disease,

- if you have liver disease. Tell your doctor if you think any of these may apply to
- Warnings and precautions Talk to your doctor or pharmacist before taking if you are pregnant or think you may be pregnant.
- if you have a serious heart complaint. if you have a serious mental health problem.

lactose).

you.

are taking it.

if you are breast-feeding. if you are under 18 years old.

behaviours (such as excessive gambling or excessive sexual behaviour). if you have an intolerance to some sugars (such as

if you have experienced any unusual urges and/or

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your ropinirole treatment

(called dopamine agonist withdrawal syndrome or

DAWS). If the problems persist more than a few

weeks, your doctor may need to adjust your

treatment. 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

behaviours such as addictive gambling, excessive

are called impulse control disorders and can include

eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. 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.

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

Your doctor may decide that Ropinirole is not suitable

for you, or that you need extra check-ups while you

- If your restless legs symptoms get worse Some people taking ropinirole 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
- Tell your doctor as soon as possible if you get any of these symptoms. Smoking and Ropinirole Tell your doctor if you start smoking, or give up

smoking, while you are taking ropinirole. Your doctor

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

Children

may need to adjust your dose.

return in the early morning.

Other medicines and Ropinirole Tell your doctor or pharmacist if you are taking, have

recently taken or might take any other medicines. Remember to tell your doctor if you start taking any

other medicine while you are taking ropinirole. Some medicines can affect the way Ropinirole works or make it more likely that you will have side effects. Ropinirole can also affect the way some other

medicines work. These include:

the anti-depressant fluvoxamine

example sulpiride

HRT (hormone replacement therapy) the antibiotics ciprofloxacin or enoxacin medication for other mental health problems, for

- heartburn
- cimetidine, used in the treatment of stomach ulcers

metoclopramide, which is used to treat nausea and

any other medicine for Parkinson's disease 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 Ropinirole:

Vitamin K antagonists (used to reduce blood clotting) such as warfarin (coumadin). Ropinirole with food and drink If you take Ropinirole with food, you may be less likely

to feel sick (nauseous) or be sick (vomit). So it is best

to take it with food if you can.

medicine.

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

Your doctor may advise you to stop taking ropinirole.

Ropinirole is not recommended if you are pregnant,

unless your doctor advises that the benefit to you of taking Ropinirole is greater than the risk to your

unborn baby. Ropinirole is not recommended if you

are breast-feeding, as it can affect your milk production. Your doctor will advise you if you are breast-feeding or planning to do so.

Ropinirole can make you feel drowsy. It can make

people fall asleep very suddenly without warning.

people feel extremely sleepy and it sometimes makes

If you could be affected: do not drive, do not operate machines and **do not** put yourself in any situation

drive or use machines.

Ropinirole contains sodium

Driving and using machines

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.

Ropinirole can cause hallucinations (seeing, hearing

or feeling things that are not there). If affected, do not

Ropinirole contains lactose If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

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 ropinirole to children. Ropinirole is not normally prescribed for people under 18.

3 How to take Ropinirole

For doses not possible with this medicinal product other strengths of this medicinal product are

Ropinirole is used differently depending on the

Parkinson's disease You may be given Ropinirole on its own to treat the symptoms of your Parkinson's disease. Or you may be

given Ropinirole as well as another medicine called

If you are taking L-dopa you may experience some

uncontrollable movements (dyskinesias) when you

first start taking Ropinirole. Tell your doctor if this happens, as your doctor may need to adjust the dose

Ropinirole for you.

L-dopa (also called levodopa).

of the medicines you are taking.

The recommended starting dose is 0.25 mg of ropinirole three times each day for the first week. Then your doctor will increase your dose each week, for the next three weeks. After that your doctor will gradually increase the dose until you are taking the

How much Ropinirole will you need to take? It may take a while to find out the best dose of

dose that is best for you. The recommended dose is 1 mg to 3 mg three times each day (making a total daily dose of 3 mg to 9 mg). If your Parkinson's disease symptoms have not improved enough, your doctor may decide to

gradually increase your dose some more. Some people take up to 8 mg of Ropinirole three times a day (24 mg daily altogether).

If you are also taking other medicines for Parkinson's disease, your doctor may advise you to gradually

Do not take any more Ropinirole than your doctor has

It may take a few weeks for Ropinirole to work for you.

Take Ropinirole three times a day. Swallow the tablets whole, with a glass of water. It is best to take Ropinirole with food, because that makes

Restless legs syndrome

Taking your dose of Ropinirole

recommended

reduce the dose of the other medicine.

How much Ropinirole will you need to take? It may take a while to find out the best dose of

it less likely that you will feel sick (nauseous).

Ropinirole for you. The recommended starting dose is 0.25 mg once a

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.

day. After two days, your doctor will probably

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 Ropinirole for

three months, your doctor may adjust your dose or

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

Carry on taking Ropinirole as your doctor advises,

even if you do not feel better. Ropinirole may take a

few weeks to work for you. Taking your dose of Ropinirole

water.

advise you to stop taking it.

Take Ropinirole once a day.

Swallow the Ropinirole tablets whole, with a glass of

(nauseous). Ropinirole is usually taken just before bedtime, but

you can take it up to 3 hours before you go to bed.

You can take Ropinirole with or without food. If you

Ropinirole dose should be individually titrated in

patients over 65 years old, with careful monitoring of tolerability, to the optimal clinical response. If you take more Ropinirole than you should Contact a doctor or pharmacist immediately. If

possible, show them the Ropinirole pack.

Someone who has taken an overdose of Ropinirole 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 Ropinirole Do not take extra tablets or a double dose to make up

usual time. Parkinson's disease: If you have missed taking Ropinirole for one day or more, ask your doctor for advice on how to start taking it again.

for a forgotten dose. Just take your next dose at the

Restless legs syndrome: If you have missed taking Ropinirole for more than a few days, ask your doctor for advice on how to start taking it again.

If you stop taking ropinirole Do not stop taking ropinirole without advice. Take Ropinirole for as long as your doctor recommends.

Do not stop unless your doctor advises you to.

disease symptoms or restless legs 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,

If you suddenly stop taking ropinirole your Parkinson's

fever, unstable blood pressure, tachycardia (increased heart rate), confusion, depressed level of consciousness (e.g. coma). If you need to stop taking Ropinirole your doctor will reduce your dose gradually. If you have any further questions on the use of this

medicine, ask your doctor or pharmacist. Possible side effects

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



The side effects of Ropinirole are more likely to happen when you first start taking it, or when your

taken the dose for a while.

hospitalisation.

dose has just been increased. They are usually mild, and may become less troublesome after you have

If you are worried about side effects, talk to your Stop taking Ropinirole and tell your doctor immediately or go to the casualty department at your nearest hospital, if the following happens: allergic reactions such as red, itchy swellings on

swallowing or breathing, rash or intense itching (see section 2). These are very serious side effects with unknown frequency. You may need urgent medical attention or

the skin (hives), swelling of the face, lips, mouth,

tongue or throat which may cause difficulty in

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

o strong impulse to gamble excessively despite serious personal or family consequences.

altered or increased sexual interest and

(frequency not known: cannot be estimated from the

You may experience the following side effects

- behaviour of significant concern to you or to others, for example, an increased sexual drive. o uncontrollable excessive shopping or spending o binge eating (eating large amounts of food in a
- more food than normal and more than is needed to satisfy your hunger) excessive use of ropinirole (craving for large doses of dopaminergic drugs in excess of that required to

control motor symptoms, known as dopamine

episodes of overactivity, elation or irritability

dysregulation syndrome)

short time period) or compulsive eating (eating

depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS) after stopping or reducing your ropinirole treatment Tell your doctor if you experience any of these

behaviours; they will discuss ways of managing or reducing the symptoms.

Parkinson's disease

heartburn

feeling sick (nausea)

Common: may affect up to 1 in 10 people

aggression

ropinirole is used to treat Parkinson's disease: Very common: may affect more than 1 in 10 people fainting feeling drowsy

Following side effects have been reported, when

being sick (vomiting) feeling dizzy (a spinning sensation)

hallucinations ('seeing' things that are not real)

stomach pain swelling of the legs, feet and hands

feeling dizzy or faint, especially when you stand

up suddenly (this is caused by a drop in blood pressure)

Uncommon: may affect up to 1 in 100 people

- low blood pressure (hypotension) · feeling very sleepy during the day (extreme somnolence)
- falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes) mental problems such as delirium (severe
- confusion), delusions (unreasonable ideas) or paranoia (unreasonable suspicions)
- Not known: frequency cannot be estimated from the available data

changes in liver function, which have shown up

- in blood tests. Spontaneous penile erection
- If you are taking Ropinirole with L-dopa People who are taking Ropinirole with L-dopa may
- develop other side effects over time: uncontrollable movements (dyskinesias) are a very common side effect. If you are taking L-dopa you

may experience some uncontrollable movements (dyskinesia) when you first start taking ropinirole.

- take it with food, you may be less likely to feel sick
- need to adjust the doses of the medicines you are taking. feeling confused is a common side effect.

Tell your doctor if this happens, as your doctor may

Restless legs syndrome:

The following side effects have been reported, when ropinirole is used to treat restless legs syndrome:

nervousness

stomach pain

in blood tests.

Very common: may affect more than 1 in 10 people

feeling sick (nausea)

- being sick (vomiting)
- Common: may affect up to 1 in 10 people
- fainting drowsiness
- fatigue (mental or physical tiredness) dizziness (a 'spinning' sensation)
 - 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) Uncommon: may affect up to 1 in 100 people 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:** may affect up to 1 in 10,000 people

falling asleep very suddenly without feeling

feeling very sleepy during the day (extreme somnolence)

sleepy first (sudden sleep onset episodes) changes in liver function which have shown up

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

mentalproblems (other than hallucinations),

ideas (delusions) and irrational suspiciousness (paranoia) spontaneous penile erection Ropinirole 0.5/2 mg film-coated tablets: lecithin (soya)

such as severe confusion (delirium), irrational

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects

may cause very rarely allergic reactions.

not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA

Yellow Card in the Google Play or Apple App Store. By

reporting side effects you can help provide more

information on the safety of this medicine. How to store Ropinirole

the original container.

0.25 mg ropinirole.

Reporting of side effects

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

Ropinirole 0.25 mg: Do not store above 25°C. Store in

Ropinirole 0.5 mg: Do not store above 25°C. Store in the original container. Ropinirole 2 mg: Do not store above 30°C. Store in the original container.

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.

Contents of the pack and other information What Ropinirole contains The active substance is ropinirole hydrochloride. Each Ropinirole 0.25 mg film-coated tablet contains

0.285 mg ropinirole hydrochloride, equivalent to

Each Ropinirole 0.5 mg film-coated tablet contains

0.57 mg ropinirole hydrochloride, equivalent to 0.5 mg ropinirole. Each Ropinirole 2 mg film-coated tablet contains 2.28 mg ropinirole hydrochloride, equivalent to 2 mg ropinirole.

The other ingredients are lactose monohydrate, microcrystalline cellulose, hydroxypropylcellulose,

croscarmellose sodium and magnesium stearate.

The tablet coating contains: Ropinirole 0.25 mg (Opadry II 85F18422): poly (vinyl alcohol) - partially hydrolyzed, titanium dioxide (E171), macrogol 3350 and talc.

Ropinirole 0.5 mg (Opadry II 85G32558): poly(vinyl

alcohol) - partially hydrolyzed, titanium dioxide

(E171), macrogol 3350, talc, lecithin (soya) (E322)

iron oxide yellow (E172) and iron oxide black (E172). Ropinirole 2 mg (Opadry II 85G34363): poly(vinyl

oxide black (E172).

plain on the other.

- alcohol) partially hydrolyzed, titanium dioxide (E171), macrogol 3350, talc, lecithin (soya) (E322), carmine (E120), iron oxide yellow (E172) and iron
- Ropinirole 0.25 mg is a white, round slightly arched film-coated tablet, debossed "R 0.25" on one side and plain on the other. Ropinirole 0.5 mg is a yellow, round slightly arched film-coated tablet, debossed "R 0.5" on one side and

What Ropinirole looks like and contents of the pack

Ropinirole 2 mg is a pink, round slightly arched film-coated tablet, debossed "R 2" on one side and plain on the other.

Ropinirole 0.25 mg is available in pack sizes of 12, 15, 21, 24, 30, 60, 81, 84, 90, 100, 126, 210 and 50 unit dose blisters (hospital presentation pack). Ropinirole 0.5 mg is available in pack sizes of 15, 21,

Ropinirole 2 mg is available in pack sizes of 15, 21, 28, 30, 60, 84, 90 and 100 and 50 unit dose blisters (hospital pack).

Marketing Authorisation Holder Teva UK Limited, Ridings Point, Whistler Drive,

Castleford, WF10 5HX, United Kingdom Manufacturer Teva Pharmaceutical Works Private Ltd Company

Hungary This leaflet was last revised in April 2025.

28, 30, 60, 84, 90, 100 and 126.

Not all pack sizes may be marketed.

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