Package leaflet: Information for the patient

Rolpryna SR 2 mg prolonged-release tablets
Rolpryna SR 4 mg prolonged-release tablets
Rolpryna SR 8 mg prolonged-release 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 Rolpryna SR is and what it is used for

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

Rolpryna SR prolonged-release tablets are used to treat Parkinson's disease.

People with Parkinson's disease have low levels of 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.

2. What you need to know before you take Rolpryna SR

Do NOT TAKE Rolpryna SR:
- 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 **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 Rolpryna SR:
- 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 a **serious heart complaint**
- if you have a serious **mental health problem**
- if you have experienced any **unusual urges and/or behaviours** (see section 4)
- if you have an intolerance to some sugars (such as lactose).

Tell your doctor if you think any of these may apply to you. Your doctor may decide that Rolpryna SR is not suitable for you, or that you need extra check-ups while you are taking it.

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. Your doctor may need to adjust or stop your dose.

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 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.

While you are taking Rolpryna SR
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 Rolpryna SR. Your doctor may need to adjust or stop your dose.

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

Other medicines and Rolpryna SR
Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 Rolpryna SR.

Some medicines can affect the way Rolpryna SR works, or make it more likely that you will have side effects. Rolpryna SR can also affect the way some other medicines work.
These include:
- the anti-depressant fluvoxamine;
- medication for other mental health problems, for example sulpiride;
- HRT (hormone replacement therapy);
- metoclopramide, which is used to treat nausea and heartburn;
- the antibiotics ciprofloxacin or enoxacin;
- any other medicine for Parkinson's disease.

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

Rolpryna SR with food and drink
You can take Rolpryna SR with or without food.

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

Tell your doctor immediately if you are pregnant, think you may 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 Rolpryna SR.

Driving and using machines
Rolpryna SR can make you feel drowsy. **It can make people feel extremely sleepy**, and it sometimes makes people **fall asleep very suddenly without warning**. Ropinirole 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.

Rolpryna SR contains lactose
If you have been told by your doctor that you have **an intolerance to some sugars**, contact your doctor before taking this medicinal product.

3. How to take Rolpryna SR

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

Use in children and adolescents
Do not give Rolpryna SR to children. Rolpryna SR is not normally prescribed for people under 18.

You may be given Rolpryna SR on its own to treat the symptoms of your Parkinson's disease. Or you may be given Rolpryna SR as well as another medicine called L-dopa (also called levodopa). If you are taking L-dopa you may experience some uncontrollable movements (dyskinesias) when you first start taking Rolpryna SR. Tell your doctor if this happens, as your doctor may need to adjust the doses of the medicines you are taking.

Rolpryna SR tablet(s) are designed to release drug over a 24 hr period. If you have a condition where your medicine passes through your body too quickly, e.g., diarrhoea, the tablet(s) may not dissolve completely and may not work properly. You may see tablet(s) in your stool. If this happens, let your doctor know as soon as possible.

How much Rolpryna SR will you need to take?

It may take a while to find out the best dose of Rolpryna SR for you.

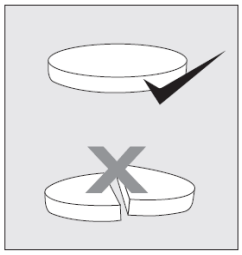
The recommended starting dose of Rolpryna SR prolonged-release tablets is 2 mg once daily for the first week. Your doctor may increase your dose to 4 mg of Rolpryna SR prolonged-release tablets once daily, from the second week of treatment. If you are very elderly, your doctor may increase your dose more slowly. After that, the doctor may adjust your dose until you are taking the dose that is best for you. Some people take up to 24 mg of Rolpryna SR prolonged-release tablets each day.

If at the start of your treatment, you experience side effects that you find difficult to tolerate, speak to your doctor. Your doctor may advise you to switch to a lower dose of ropinirole immediate-release tablets which you will take three times a day.

Do not take any more Rolpryna SR than your doctor has recommended.

It may take a few weeks for Rolpryna SR to work for you.

Taking your dose of Rolpryna SR



Take Rolpryna SR **once a day**, at the same time each day.

Swallow your Rolpryna SR prolonged-release tablet(s) whole, with a glass of water.

DO NOT break, chew or crush the prolonged-release tablet(s). If you do, there is a danger you could overdose, because the medicine will be released into your body too quickly.

If you are switching from ropinirole immediate-release tablets
Your doctor will base your dose of Rolpryna SR prolonged-release tablets on the dose of ropinirole immediate-release tablets you were taking.

Take your ropinirole immediate-release tablets as normal the day before you switch. Then take your Rolpryna SR prolonged-release tablets next morning and do not take any more ropinirole immediate-release tablets.

If you take more Rolpryna SR than you should
Contact a doctor or pharmacist immediately. If possible, show them the Rolpryna SR pack.

Someone who has taken an overdose of Rolpryna SR 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 Rolpryna SR
Do not take extra prolonged-release tablets or a double dose to make up for a forgotten dose.
If you have missed taking Rolpryna SR for one day or more, ask your doctor for advice on how to start taking it again.

If you stop taking Rolpryna SR
Do not stop taking Rolpryna SR without talking to your doctor.
Take Rolpryna SR for as long as your doctor recommends. Do not stop unless your doctor advises you to.
If you suddenly stop taking Rolpryna SR, your Parkinson's disease 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 Rolpryna SR, 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.

The side effects of Rolpryna SR 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 are worried about side effects, talk to your doctor.

Very common side effects (may affect more than 1 in 10 people)
- fainting

- feeling drowsy
- feeling sick (nausea).

Common side effects (may affect up to 1 in 10 people)
- falling asleep very suddenly without feeling sleepy first (sudden sleep onset episodes)
- hallucinations ('seeing' things that are not really there)
- being sick (vomiting)
- feeling dizzy (a spinning sensation)
- heartburn
- stomach pain
- constipation
- swelling of the legs, feet or hands.

Uncommon side effects (may affect up to 1 in 100 people)
- feeling dizzy or faint, especially when you stand up suddenly (this is caused by a drop in blood pressure)
- low blood pressure (hypotension)
- feeling very sleepy during the day (extreme somnolence)
- mental problems such as delirium (severe confusion), delusions (unreasonable ideas) or paranoia (unreasonable suspicions)
- hiccups.

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)
- changes in liver function, which have shown up in blood tests.
- act in an aggressive manner
- excessive use of Rolpryna SR (craving for large doses of dopaminergic drugs in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome)
- 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 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 normal and more than is needed to satisfy your hunger).
- depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS) after stopping or reducing your Rolpryna SR treatment
- episodes of overactivity, elation or irritability
- spontaneous penile erection.

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

If you are taking Rolpryna SR with L-dopa
People who are taking Rolpryna SR 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 (dyskinesias) when you first start taking Rolpryna SR. Tell your doctor if this happens, as your doctor may need to adjust the doses of the medicines you are taking.
- feeling confused is a common side effect.

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rolpryna SR

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

Do not store above 30 °C.
Store in the original package in order to protect from moisture.

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 Rolpryna SR contains
- The active substance is ropinirole.
  Rolpryna SR 2 mg prolonged-release tablets:
  Each prolonged-release tablet contains 2 mg ropinirole (as hydrochloride).

  Rolpryna SR 4 mg prolonged-release tablets:
  Each prolonged-release tablet contains 4 mg ropinirole (as hydrochloride).

  Rolpryna SR 8 mg prolonged-release tablets:
  Each prolonged-release tablet contains 8 mg ropinirole (as hydrochloride).

- The other ingredients are:
  Rolpryna SR 2 mg prolonged-release tablets:
  hypromellose type 2208, lactose monohydrate, colloidal anhydrous silica, carbomers 4,000-11,000 mPa.s, hydrogenated castor oil, magnesium stearate in the tablet core and hypromellose type 2910, titanium dioxide (E171), macrogol 400, red iron oxide (E172), yellow iron oxide (E172) in the film-coating.
  See section 2. "Rolpryna SR contains lactose."

  Rolpryna SR 4 mg and 8 mg prolonged-release tablets:
  hypromellose type 2208, lactose monohydrate, colloidal anhydrous silica, carbomers 4,000-11,000 mPa.s, hydrogenated castor oil, magnesium stearate in the tablet core and hypromellose type 2910, titanium dioxide (E171), macrogol 400, red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172) in the film-coating.
  See section 2. "Rolpryna SR contains lactose."

What Rolpryna SR looks like and contents of the pack
Rolpryna SR 2 mg prolonged-release tablets:
Tablets are pink, biconvex and oval.
Rolpryna SR 4 mg prolonged-release tablets:
Tablets are light off-brown, biconvex and oval.
Rolpryna SR 8 mg prolonged-release tablets:
Tablets are brownish-red, biconvex and oval.

Tablets are available in cartons of 10, 21, 28, 30, 42, 60, 84 and 90 prolonged-release tablets in blisters (OPA/Alu/PVC//Alu).
Not all pack sizes may be marketed.

Marketing Authorisation Holder
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturers
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the Member State	Name of the medicine
Austria, Denmark, Finland, Spain, Netherlands, Slovak republic, Sweden	Ropinirol Krka
Ireland	Rolpryna SR
Italy	Ropinirolo Krka

This leaflet was last revised in