

Package leaflet: Information for the user

Pramipexole-ratiopharm® 0.088 mg tablets

Pramipexole-ratiopharm® 0.18 mg tablets

Pramipexole-ratiopharm® 0.35 mg tablets

Pramipexole-ratiopharm® 0.7 mg tablets

Active substance: Pramipexole

Read the entire package leaflet carefully before you start taking this medicine.

- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this package leaflet, please tell your doctor or pharmacist.

This package leaflet contains:

1. What is Pramipexol-ratiopharm® and what is it used for?
2. What should you consider before taking Pramipexol-ratiopharm®?
3. How should Pramipexol-ratiopharm® be taken?
4. What side effects are possible?
5. How should Pramipexol-ratiopharm® be stored?
6. Further information

1. WHAT IS Pramipexol-ratiopharm® AND WHAT IS IT USED FOR?

Pramipexol-ratiopharm® belongs to the group of dopamine agonists that stimulate the dopamine receptors of the brain stimulate. The stimulation of dopamine receptors triggers nerve impulses in the brain that help control body movements.

Pramipexol-ratiopharm® is used for the

- treatment of symptoms in idiopathic Parkinson's disease. It can be used either alone or in combination with Levodopa.

2. WHAT SHOULD YOU CONSIDER BEFORE TAKING Pramipexol-ratiopharm®?

Pramipexol-ratiopharm® must not be taken

- if you are hypersensitive (allergic) to pramipexole or any of the other ingredients of Pramipexol-ratiopharm® (see section 6 under "What Pramipexol-ratiopharm® contains").

Special caution is required when taking Pramipexol-ratiopharm®

Please inform your doctor if you have (had) or develop any complaints or symptoms, especially in the following cases:

- Kidney disease
- Hallucinations (seeing, hearing, or feeling things that are not there). Most hallucinations are visual Art.

- Dyskinesias (e.g., abnormal, uncontrolled movements of the limbs). If you have advanced Parkinson's disease and are also taking Levodopa, you may develop motor dysfunctions (dyskinesias) during the gradual increase of the dosage of Pramipexol-ratiopharm®.
- Drowsiness and sudden sleep attacks
- Behavioral changes (e.g., pathological gambling, compulsive shopping), increased libido (e.g., heightened sexual desire), binge eating
- Psychosis (e.g., comparable to symptoms like schizophrenia)
- Visual disturbances. Have your eyes examined regularly during treatment with Pramipexol-ratiopharm®. Examine at intervals.
- of the treatment. This is to prevent a drop in blood pressure upon standing (orthostatic hypotension). Children and adolescents be.

Taking Pramipexol-ratiopharm® with other medicines

Please inform your doctor or pharmacist if you are taking/using or have recently taken/used other medicines. This includes medicines, herbal remedies, health foods, or

dietary supplements that are not prescription-only.

You should avoid taking Pramipexol-ratiopharm® together with antipsychotic medicines. Be cautious when taking the following medicines: Dietary supplements that are not prescription-only.

You should avoid taking Pramipexol-ratiopharm® together with antipsychotic medications.

Be careful when taking the following medications:

- Cimetidine (for the treatment of increased stomach acid and stomach ulcers)
- Amantadine (can be used for the treatment of Parkinson's disease)
- Mexiletine (for the treatment of irregular heartbeat, known as ventricular arrhythmia)

If you are taking Levodopa, a reduction in the dose of Levodopa is recommended at the start of treatment with Pramipexole-ratiopharm®.

Be careful if you are taking medicines with a calming (sedative) effect or if you drink alcohol. In these cases, Pramipexole-ratiopharm® may impair your ability to drive or operate machinery.

When taking Pramipexole-ratiopharm® with food and drink

Be careful if you drink alcohol during treatment with Pramipexole-ratiopharm®. Pramipexole-ratiopharm® can be taken with or without food. Take the tablets with water.

Pregnancy and breastfeeding

Pregnancy and lactation

The effect of Pramipexole-ratiopharm® on the unborn child is not known. Therefore, do not take Pramipexole-ratiopharm® if you are pregnant, unless your doctor gives you specific instructions. Pramipexole-ratiopharm® should not be taken during breastfeeding. Pramipexole-ratiopharm® can inhibit milk production. Furthermore, it can pass into breast milk and reach the infant. If treatment with Pramipexole-ratiopharm® is deemed necessary, breastfeeding should be discontinued. Ask your doctor or pharmacist for advice before taking any medicines. Ability to drive and use machines

Consult your doctor or pharmacist before taking any medications.

Driving ability and operating machinery

Pramipexole-ratiopharm® can cause hallucinations (seeing, hearing, or feeling things that are not there). If you are affected, you must not drive or operate machinery.

Pramipexole-ratiopharm® is associated with drowsiness and sudden sleep attacks, especially in patients with Parkinson's disease. If such side effects occur, you must not drive or operate machinery. Please inform your doctor if these side effects occur.

3. HOW TO TAKE Pramipexole-ratiopharm®

Always take Pramipexole-ratiopharm® exactly as your doctor has instructed. Your doctor will advise you on the correct dosage.

Pramipexole-ratiopharm® can be taken with or without food. Take the tablets with water.

Parkinson's disease

The total daily dose is divided into three equal doses.

During the first week, the usual dose is 1 tablet of Pramipexole-ratiopharm® 0.088 mg three times a day (corresponding to a daily dose of 0.264 mg):

	First week
Number of tablets day	1 tablet of Pramipexole-ratiopharm® 0.088 mg three times a
Total daily dose (mg)	0.264

The daily dose is increased every 5 – 7 days as instructed by your doctor until your symptoms are under control (maintenance dose).

	Second week	Third week
Number of tablets	3 x daily 1 tablet Pramipexol-ratiopharm® 0.18 mg OR 3 x daily 2 tablets Pramipexol-ratiopharm® 0.088 mg	3 x daily 1 tablet Pramipexol-ratiopharm ® 0.35 mg OR 3 x daily 2 tablets Pramipexol-ratiopharm® 0.18 mg
Total daily dose (mg)	0.54	1.1

The usual maintenance dose is 1.1 mg per day. However, your dose may need to be increased further. Your doctor may increase the dose to a maximum of 3.3 mg Pramipexol per day if necessary. A lower maintenance dose of 3 tablets of Pramipexol-ratiopharm® 0.088 mg per day is also possible.

	Lowest maintenance dose	Highest maintenance dose
Number of tablets	3 times daily 1 tablet Pramipexole-ratiopharm® 0.088 mg 0.35 mg	3 times daily 3 tablets Pramipexole-ratiopharm®
Total daily dose (mg)	0.264	3.3

Patients with kidney disease

If you have moderate or severe kidney disease, your doctor will prescribe a lower dose. In this case, you only need to take the tablets 1 or 2 times daily. For moderate kidney disease, the usual starting dose is 1 tablet of Pramipexole-ratiopharm® 0.088 mg twice daily. For severe kidney disease, the usual starting dose is 1 tablet of Pramipexole-ratiopharm® 0.088 mg once daily.

If you have taken more Pramipexole-ratiopharm® than you should

If you accidentally take too many tablets,

- contact your doctor or the emergency department of the nearest hospital immediately.
- you may develop vomiting, restlessness, or other side effects described in section 4.

"What side effects are possible?"

If you forget to take Pramipexole-ratiopharm®

Continue the treatment at the next scheduled time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Pramipexole-ratiopharm®

Do not stop taking Pramipexole-ratiopharm® without first talking to your doctor. If you need to stop taking this medication, your doctor will gradually reduce the dose. This will reduce the risk of worsening symptoms.

If you have Parkinson's disease, you should not stop treatment with Pramipexole-ratiopharm® suddenly. Sudden discontinuation can cause a condition called neuroleptic malignant syndrome, which can pose a significant health risk. Symptoms include: akinesia (reduced or absent muscle movement), muscle stiffness, fever, unstable blood pressure, tachycardia (increased heart rate), confusion, impaired consciousness (e.g., coma).

If you have further questions about the use of the medication, ask your doctor or pharmacist.

4. WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicines, Pramipexole-ratiopharm® can have side effects, but not everyone will experience them.

If you suffer from Parkinson's disease, the following side effects may occur:

Very common (more than 1 in 10 treated patients)

- Dyskinesia (e.g., abnormal, uncontrolled movements of the limbs), drowsiness, dizziness
- Hypotension (low blood pressure)
- Nausea

Common (1 to 10 in 100 treated patients)

- abnormal dreams, urge to behave unusually, hallucinations (seeing, hearing, or feeling things that are not there), confusion, insomnia, restlessness
- Amnesia (memory impairment), headache
- Visual disturbances
- Constipation, vomiting
- Fatigue, fluid retention in tissues, usually in the legs (peripheral edema)
- Weight loss

Occasional (1 to 10 in 1,000 treated patients)

Pneumonia

compulsive shopping, delusions, hypersexuality, increased sexual desire (e.g., increased libido), paranoia (e.g., excessive concern for one's own well-being), pathological gambling, especially if you take high doses of Pramipexole-ratiopharm®

Hyperkinesia (increased urge to move and inability to stay still), excessive drowsiness during the day and sudden sleep onset, fainting spells

Dyspnea (shortness of breath)

allergic reactions (e.g., rash, itching, hypersensitivity)

Weight gain

Not known (frequency cannot be estimated from the available data)

increased eating (binge eating, hyperphagia)

Please inform your doctor or pharmacist if any of the listed side effects significantly affect you or if you notice side effects not listed in this leaflet.

5. HOW TO STORE Pramipexol-ratiopharm®?

Keep medicines out of the reach of children.

Do not use the medicine after the expiry date stated on the carton and blister packs. The expiry date refers to the last day of the month.

Do not store above 25 °C.

Store in the original package to protect the contents from light.

Do not dispose of the medicine in wastewater or household waste. Ask your pharmacist how to dispose of the medicine when you no longer need it. This measure helps protect the environment.

6. FURTHER INFORMATION

What Pramipexol-ratiopharm® contains

The active substance is pramipexole.

Each tablet contains

- Pramipexol-ratiopharm® 0.088 mg tablets: 0.088 mg pramipexole (as 0.125 mg pramipexole dihydrochloride 1 H₂O)
- Pramipexol-ratiopharm® 0.18 mg tablets: 0.18 mg pramipexole (as 0.25 mg pramipexole dihydrochloride 1 H₂O)
- Pramipexol-ratiopharm® 0.35 mg tablets: 0.35 mg pramipexole (as 0.5 mg pramipexole dihydrochloride 1 H₂O)
- Pramipexol-ratiopharm® 0.7 mg tablets: 0.7 mg pramipexole (as 1.0 mg pramipexole dihydrochloride 1 H₂O).

The content of your tablet is indicated on the outer carton.

The other ingredients are:

Povidone K30, microcrystalline cellulose, corn starch, magnesium stearate (Ph.Eur.), silicon dioxide.

What Pramipexol-ratiopharm® looks like and contents of the pack

Pramipexol-ratiopharm® 0.088 mg tablets
White, round, flat tablet with beveled edges.

Pramipexol-ratiopharm® 0.18 mg tablets
White, oval, flat tablet with beveled edges and score lines on both sides. The tablet can be divided into equal halves.

Pramipexol-ratiopharm® 0.35 mg tablets
White, oval, flat tablet with beveled edges and score lines on both sides. The tablet can be divided into equal halves.

Pramipexol-ratiopharm® 0.7 mg tablets
White, round, flat tablet with beveled edges and score lines on both sides. The tablet can be divided into equal halves.

Pramipexol-ratiopharm® 0.088 mg tablets are available in packs of 30 tablets.
Pramipexol-ratiopharm® 0.18 mg tablets are available in packs of 30, 100, and 200 tablets.
Pramipexol-ratiopharm® 0.35 mg tablets are available in packs of 30, 100, and 200 tablets.
Pramipexol-ratiopharm® 0.7 mg tablets are available in packs of 100 and 200 tablets.

Pharmaceutical entrepreneur
ratiopharm GmbH
Graf-Arco-Str. 3
89079 Ulm

Manufacturer
Merckle GmbH
Ludwig-Merckle-Str. 3
89143 Blaubeuren

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