

Pramipexole 0.088mg Tablets

Pramipexole 0.18mg Tablets

Pramipexole 0.7mg Tablets

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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What pramipexole is and what it is used for
2. What you need to know before you take pramipexole
3. How to take pramipexole
4. Possible side effects
5. How to store pramipexole
6. Contents of the pack and other information

1. WHAT PRAMIPEXOLE IS AND WHAT IT IS USED FOR

The name of your medicine is Pramipexole 0.088mg, 0.18mg or 0.7mg Tablets (referred to as pramipexole throughout this leaflet). Pramipexole Tablets contain the active substance pramipexole and belong to a group of medicines known as dopamine agonists, which stimulate dopamine receptors in the brain. Stimulation of the dopamine receptors triggers nerve impulses in the brain that help to control body movements.

Pramipexole is used to:

- treat the symptoms of primary Parkinson's disease in adults. It can be used alone or in combination with levodopa (another medicine for Parkinson's disease).

Pramipexole may also be authorised to treat other conditions which are not mentioned in this leaflet. Ask your doctor or pharmacist if you have further questions.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PRAMIPEXOLE

Do not take pramipexole

- if you are allergic to pramipexole or to any of the other ingredients in this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor before taking pramipexole. Tell your doctor if you have (had) or develop any medical conditions or symptoms, especially any of the following:

- Kidney disease.
- Hallucinations (seeing, hearing or feeling things that are not there). Most hallucinations are visual.
- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs). If you have advanced Parkinson's disease and are also taking levodopa, you might develop dyskinesia during the up-titration of pramipexole.
- Sleepiness and episodes of suddenly falling asleep.
- Psychosis, (e.g. comparable with symptoms of schizophrenia).
- Vision impairment. You should have regular eye examinations during treatment with pramipexole.
- Severe heart or blood vessel disease. You will need to have your blood pressure checked regularly, especially at the beginning of treatment. This is to avoid postural hypotension (a fall in blood pressure on standing up).
- Augmentation. You may experience that symptoms start earlier than usual, be more intense and involve other limbs

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 preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

Children and adolescents

Pramipexole is not recommended for use in children or adolescents under 18 years.

Other medicines and pramipexole

Tell your doctor or pharmacist, if you are taking, have recently taken or might take any other medicines. This includes medicines, herbal remedies, health foods or supplements that you have obtained without a prescription.

You should avoid taking pramipexole together with antipsychotic medicines.

Take care if you are taking the following medicines:

- cimetidine (to treat excess stomach acid and stomach ulcers)
- amantadine (which can be used to treat Parkinson's disease)
- mexiletine (to treat irregular heartbeats, a condition known as ventricular arrhythmia)
- zidovudine (which can be used to treat the acquired immune deficiency syndrome (AIDS), a disease of the human immune system);
- cisplatin (to treat various types of cancers);
- quinine (which can be used for the prevention of painful night-time leg cramps and for the treatment of a type of malaria known as falciparum malaria (malignant malaria));
- procainamide (to treat irregular heart beat).

If you are taking levodopa, it is recommended that the dose of levodopa is reduced when you start treatment with pramipexole.

Take care if you are using any medicines that calm you down (have a sedative effect) or if you are drinking alcohol. In these cases pramipexole may affect your ability to drive and operate machinery.

Pramipexole with food, drink and alcohol

You should be cautious while drinking alcohol during treatment with pramipexole. Pramipexole can be taken with or without food. Swallow the tablets with water.

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 medicine. Your doctor will then discuss with you if you should continue to take pramipexole.

The effect of pramipexole on the unborn child is not known. Therefore, do not take pramipexole if you are pregnant unless your doctor tells you to do so.

Pramipexole should not be used during breast-feeding. Pramipexole can reduce the production of breast milk. Also, it can pass into the breast milk and can reach your baby. If use of pramipexole is unavoidable, breast-feeding should be stopped.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Pramipexole can cause hallucinations (seeing, hearing or feeling things that are not there). If affected, do not drive or use machines. Pramipexole has been associated with sleepiness and episodes of suddenly falling asleep, particularly in patients with Parkinson's disease. If you experience these side effects, you must not drive or operate machinery. You should tell your doctor if this occurs.

3. HOW TO TAKE PRAMIPEXOLE

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The doctor will advise you on the right dosing.

You can take pramipexole with or without food. Swallow the tablets with water.

Parkinson's disease

The daily dose is to be taken divided into 3 equal doses.

During the first week, the usual dose is 1 pramipexole 0.088mg tablet three times a day (equivalent to 0.264mg daily):

	1 st week
Number of tablets	1 pramipexole 0.088mg tablet three times a day
Total daily dose (mg)	0.264

This will be increased every 5 - 7 days as directed by your doctor until your symptoms are controlled (maintenance dose).

	2 nd week	3 rd week
Number of tablets	1 pramipexole 0.18mg tablet three times a day OR 2 pramipexole 0.088mg tablets three times a day	1 pramipexole 0.35mg tablet three times a day OR 2 pramipexole 0.18mg tablets three times a day
Total daily dose (mg)	0.54	1.1

The usual maintenance dose is 1.1mg per day. However, your dose may have to be increased even further. If necessary, your doctor may increase your tablet dose up to a maximum of 3.3mg of pramipexole a day. A lower maintenance dose of three pramipexole 0.088mg tablets a day is also possible.

	Lowest maintenance dose	Highest maintenance dose
Number of tablets	1 pramipexole 0.088mg tablet three times a day	1 pramipexole 1.1mg tablet three times a day
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 will have to take the tablets only once or twice a day. If you have moderate kidney disease, the usual starting dose is 1 pramipexole 0.088mg tablet twice a day. In severe kidney disease, the usual starting dose is just 1 pramipexole 0.088mg tablet a day.

If you take more pramipexole than you should

If you accidentally take too many tablets
- contact your doctor or nearest hospital casualty department immediately for advice.
- you may experience vomiting, restlessness, or any of the side effects as described in section 4 "Possible side effects".

If you forget to take pramipexole

Do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not try to make up for the missed dose.

If you stop taking pramipexole

Do not stop taking pramipexole without first talking to your doctor. If you have to stop taking this medicine, your doctor will reduce the dose gradually. This reduces the risk of worsening symptoms.

If you suffer from Parkinson's disease you should not stop treatment with pramipexole abruptly. 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 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 everybody gets them.

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

Very common (may affect more than 1 in 10 people)

- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- Sleepiness
- Dizziness
- Nausea (feeling sick)

Common (may affect up to 1 in 10 people)

- Urge to behave in an unusual way
- Hallucinations (seeing, hearing or feeling things that are not there)
- Confusion
- Tiredness (fatigue)
- Sleeplessness (insomnia)
- Excess of fluid, usually in the legs (peripheral oedema)
- Headache
- Hypotension (low blood pressure)
- Abnormal dreams
- Constipation
- Visual impairment
- Vomiting (being sick)
- Weight loss including decreased appetite

Uncommon (may affect up to 1 in 100 people)

- Paranoia (e.g. excessive fear for one's own well-being)
- Delusion
- Excessive daytime sleepiness and suddenly falling asleep
- Amnesia (memory disturbance)
- Hyperkinesia (increased movements and inability to keep still)
- Weight increase
- Allergic reactions (e.g. rash, itching, hypersensitivity)
- Fainting
- Cardiac failure (heart problems which can cause shortness of breath or ankle swelling)*
- Inappropriate antidiuretic hormone secretion*
- Restlessness
- Dyspnoea (difficulty to breathe)
- Hiccups
- Pneumonia (infection of the lungs)
- 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)*

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

For the side effects marked with * a precise frequency estimation is not possible, since these side effects were not observed in clinical studies among 2,762 patients treated with pramipexole. The frequency category is probably not greater than "uncommon".

If you suffer from **other conditions treated with pramipexole**, you may experience the following side effects:

Very common (may affect more than 1 in 10 people)

- Nausea (sickness)

Common (may affect up to 1 in 10 people)

- Changes in sleep pattern, such as sleeplessness (insomnia) and sleepiness
- Tiredness (fatigue)
- Headache
- Abnormal dreams
- Constipation
- Dizziness
- Vomiting (being sick)

Uncommon (may affect up to 1 in 100 people)

- Urge to behave in an unusual way*

- Cardiac failure (heart problems which can cause shortness of breath or ankle swelling)*
- Inappropriate antidiuretic hormone secretion*
- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- Hyperkinesia (increased movements and inability to keep still)*
- Paranoia (e.g. excessive fear for one's own well-being)*
- Delusion*
- Amnesia (memory disturbance)*
- Hallucinations (seeing, hearing or feeling things that are not there)
- Confusion
- Excessive daytime sleepiness and suddenly falling asleep
- Weight increase
- Hypotension (low blood pressure)
- Excess of fluid, usually in the legs (peripheral oedema)
- Allergic reactions (e.g. rash, itching, hypersensitivity)
- Fainting
- Restlessness
- Visual impairment
- Weight loss including decreased appetite
- Dyspnoea (difficulties to breath)
- Hiccups
- Pneumonia (infection of the lungs)*
- 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)*

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

For the side effects marked with * a precise frequency estimation is not possible, since these side effects were not observed in clinical studies among 1,395 patients treated with pramipexole. The frequency category is probably not greater than "uncommon".

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

5. HOW TO STORE PRAMIPEXOLE

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

This medicinal product does not require any special temperature storage conditions.

Store in the 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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What pramipexole contains

The active substance is pramipexole.

0.088mg tablet: Each tablet contains 0.088 mg of pramipexole base as 0.125 mg pramipexole dihydrochloride monohydrate.
0.18mg tablet: Each tablet contains 0.18mg of pramipexole base as 0.25 mg pramipexole dihydrochloride monohydrate.
0.7mg tablet: Each tablet contains 0.7mg of pramipexole base as 1.0 mg pramipexole dihydrochloride monohydrate.

The other ingredients are: mannitol, maize starch, hydroxypropylcellulose, colloidal anhydrous silica, magnesium stearate.

What pramipexole looks like and contents of the pack

0.088mg tablets: white, round, flat tablet with a diameter of 6.5mm approximately.
0.18mg tablets: white, biconvex, oblong, scored on both sides tablet with dimensions 8mm x 4mm approximately.
0.7mg tablets: white, round, flat, scored on one side, tablet with a diameter of 9mm approximately.

Pramipexole 0.18mg and 0.7mg tablets: The tablet can be divided into equal doses.

Pramipexole is available in blister packs of 30 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

Manufacturer:
Specifar S.A., 1, 28 Octovriou str., Ag. Varvara, 12351 Athens, Greece

Or

Zentiva a.s., Nitrianska 100, 920 27 Hlohovec, Slovak Republic

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