

## **Package leaflet: Information for the user**

**Pramipexole Accord 0.088 mg tablets**

**Pramipexole Accord 0.18 mg tablets**

**Pramipexole Accord 0.35 mg tablets**

**Pramipexole Accord 0.7 mg tablets**

**Pramipexole Accord 1.1 mg tablets**

Pramipexole

**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. See section 4

### **What is in this leaflet:**

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

### **1. What Pramipexole Accord is and what it is used for**

Pramipexole Accord contains the active substance pramipexole and belongs 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 Accord 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).

### **2. What you need to know before you take Pramipexole Accord**

#### **Do not take Pramipexole Accord:**

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

#### **Warnings and precautions:**

Talk to your doctor before taking Pramipexole Accord. 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 Accord.
- 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 Accord.
- Severe heart or blood vessels 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.

Tell your doctor if you or your family/carer notices that you are developing mania (agitation, feeling elated or over-excited) or delirium (decreased awareness, confusion, loss of reality). Your doctor may need to adjust or stop your dose.

### **Children and adolescents**

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

### **Other medicines and Pramipexole Accord**

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 Accord 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, the dose of levodopa is recommended to be reduced when you start treatment with Pramipexole Accord.

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 Accord may affect your ability to drive and operate machinery.

### **Pramipexole Accord with food, drink and alcohol**

You should be cautious while drinking alcohol during treatment with Pramipexole Accord. Pramipexole Accord can be taken with or without food.

### **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 for advice before taking this medicine. Your doctor will then discuss with you if you should continue to take Pramipexole Accord.

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

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

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

### **Driving and using machines**

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

Pramipexole Accord 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 Accord**

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 Accord 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 tablet Pramipexole Accord 0.088 mg three times a day (equivalent to 0.264 mg daily):

	1 <sup>st</sup> week
Number of tablets	1 Pramipexole Accord tablet 0.088 mg 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 <sup>nd</sup> week	3 <sup>rd</sup> week
Number of tablets	1 Pramipexole Accord tablet 0.18 mg three times a day OR 2 Pramipexole Accord tablets 0.088 mg three times a day	1 Pramipexole Accord tablet 0.35 mg three times a day OR 2 Pramipexole Accord tablets 0.18 mg three times a day
Total daily dose (mg)	0.54	1.1

The usual maintenance dose is 1.1 mg 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 3.3 mg of pramipexole a day. A lower maintenance dose of three Pramipexole Accord 0.088 mg tablets a day is also possible.

	Lowest maintenance dose	Highest maintenance dose
Number of tablets	1 Pramipexole Accord tablet 0.088 mg three times a day	1 Pramipexole Accord tablet 1.1 mg 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 Accord tablet 0.088 mg twice a day. In severe kidney disease, the usual starting dose is just 1 Pramipexole Accord tablet 0.088 mg a day.

### **If you take more Pramipexole Accord 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 chapter 4 “Possible side effects”.

### **If you forget to take Pramipexole Accord**

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 Accord**

Do not stop taking Pramipexole Accord 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 Accord 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. Evaluation of these side effects is based on the following frequencies:

Very common	may affect more than 1 in 10 people
Common	may affect up to 1 in 10 people
Uncommon	may affect up to 1 in 100 people
Rare	may affect up to 1 in 1,000 people
Very rare	may affect up to 1 in 10,000 people
Not known	frequency cannot be estimated from the available data

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

### **Very common:**

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

### **Common:**

- 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:**

- 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 (difficulties 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)\*
- Delirium (decreased awareness, confusion, loss of reality)

**Rare:**

- Mania (agitation, feeling elated or over excited)

**Tell your doctor if you experience any of these behaviors; 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 indication, you may experience the following side effects:*

**Very common:**

- Nausea (sickness)

**Common:**

- Changes in sleep pattern, such as sleeplessness (insomnia) and sleepiness

- Tiredness (fatigue)
- Headache
- Abnormal dreams
- Constipation
- Dizziness
- Vomiting (being sick)

**Uncommon:**

- 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 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)\*
- Mania (agitation, feeling elated or over excited)\*
- Delirium (decreased awareness, confusion, loss of reality)\*

**Tell your doctor if you experience any of these behaviors; 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".

**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 national reporting system listed in Appendix V\*. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Pramipexole Accord

- 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 after EXP. The expiry date refers to the last day of that month.
- Store below 30°C. 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 to protect the environment.

## 6. Contents of the pack and other information

### What Pramipexole Accord tablet contains:

The active ingredient is pramipexole.

Each tablet contains 0.125 mg pramipexole dihydrochloride monohydrate equivalent to 0.088 mg pramipexole.

Each tablet contains 0.25 mg pramipexole dihydrochloride monohydrate equivalent to 0.18 mg pramipexole.

Each tablet contains 0.5 mg pramipexole dihydrochloride monohydrate equivalent to 0.35 mg pramipexole.

Each tablet contains 1.0 mg pramipexole dihydrochloride monohydrate equivalent to 0.7 mg pramipexole.

Each tablet contains 1.5 mg pramipexole dihydrochloride monohydrate equivalent to 1.1 mg pramipexole.

The other ingredients are mannitol, cellulose microcrystalline, maize starch, silica colloidal anhydrous, povidone K 30 and magnesium stearate.

### What Pramipexole Accord tablet looks like and contents of the pack

0.088 mg:

White to off-white, round, flat faced, bevel edged, with inscription 'I1' on one side and plain on the other side.

0.18 mg:

White to off-white, round, flat faced, bevel edged, with inscription 'I' and '2' on either side of the breakline on one side and breakline on the other side.

0.35 mg:

White to off-white, round, flat faced, bevel edged, with inscription 'I' and '3' on either side of the breakline on one side and breakline on the other side.

0.7 mg:

White to off-white, round, flat faced, bevel edged, with inscription 'I' and '4' on either side of the breakline on one side and breakline on the other side..

1.1 mg:

White to off-white, round, flat faced, bevel edged, with inscription 'I' and '5' on either side of the breakline on one side and breakline on other side.

All the strengths of Pramipexole Accord tablets are available in alu-alu (PVC) blisters of 10 tablets per strip, in cartons containing 3 or 10 blister strips (30 or 100 tablets).

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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**Manufacturer:**

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Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>.