

# Pramipexole 0.088 mg Tablets

# Pramipexole 0.18 mg Tablets

# Pramipexole 0.35 mg Tablets

# Pramipexole 0.7 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.

## 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

Pramipexole 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 is used to:

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

### 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 of 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.
- Behavioural changes (e.g. pathological gambling, compulsive shopping), increased libido (e.g. increased sexual desire), binge eating. 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.*
- Psychosis (e.g. comparable with symptoms of schizophrenia).
- Vision impairment.  
You should have regular eye examinations during treatment with Pramipexole.
- 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.

#### 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 (such as amisulpride or haloperidol).

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).

If you are taking levodopa, the dose of levodopa is recommended to be 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 breastfeeding

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.

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.

#### 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 0.088 mg three times a day (equivalent to 0.264 mg daily):

1st week	
Number of tablets	1 tablet Pramipexole 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).

	2nd week	3rd week
Number of tablets	1 tablet Pramipexole 0.18 mg three times a day OR 2 tablets Pramipexole 0.088 mg three times a day	1 tablet Pramipexole 0.35 mg three times a day OR 2 tablets Pramipexole 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 0.088 mg tablets a day is also possible.

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

Pramipexole is for oral use.

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

#### 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 chapter 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:

- loss of muscle movement,
- rigid muscles,
- fever,
- unstable blood pressure,
- 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, Pramipexole can cause side effects, although not everybody gets them.

#### You may experience the following side effects:

- 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.
  - o Altered or increased sexual interest and 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 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; they will discuss ways of managing or reducing the symptoms

*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 (sickness)
- Hypotension (low blood pressure)

#### 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)
- Headache
- Abnormal dreams
- Constipation
- Restlessness
- Amnesia (memory loss)
- Visual disturbance
- Vomiting (being sick)
- Weight loss

#### 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
- Hyperkinesia (increased movements and inability to keep still)
- Weight increase
- Increased sexual desire (e.g. increased libido)
- Allergic reactions (e.g. rash, itching, hypersensitivity)
- Fainting
- Pathological gambling, especially when taking high doses of Pramipexole
- Hypersexuality
- Inappropriate antidiuretic hormone secretion
- Compulsive shopping
- Dyspnoea (difficulties to breathe)
- Pneumonia (infection of the lungs)

#### Unknown frequency (frequency cannot be estimated from the available data):

- Increased eating (binge eating, )

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

Store in the original package 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 further information

#### What Pramipexole contains

The active substance is pramipexole.

Each tablet contains 0.088 mg, 0.18 mg, 0.35 mg, or 0.7 mg as 0.125 mg, 0.25 mg, 0.5 mg, or 1.0 mg pramipexole dihydrochloride monohydrate, respectively.

The other ingredients are: mannitol, maize starch, silica, colloidal anhydrous, pregelatinized maize starch, povidone K-30, magnesium stearate.

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

##### Pramipexole 0.088 mg tablets

Pramipexole 0.088 mg tablets are white to off white, round, flat, bevel edged, uncoated tablets, debossed "P1" on one side and plain on other side.

##### Pramipexole 0.18 mg tablets

Pramipexole 0.18 mg tablets are white to off white, round, flat, bevel edged, uncoated tablets, debossed with "P2" on both sides of break line on one side and plain on other side. The tablets can be divided into equal halves.

##### Pramipexole 0.35 mg tablets

Pramipexole 0.35 mg tablets are white to off white, round, biconvex, uncoated tablets, debossed with "P3" on both sides of break line on one side and plain break line on other side. The tablets can be divided into equal halves.

##### Pramipexole 0.7 mg tablets

Pramipexole 0.7 mg tablets are white to off white, round, flat, bevel edged, uncoated tablets, debossed with "P5" on both sides of break line on one side and plain on other side. The tablets can be divided into equal halves.

All strengths are available in packs containing 20, 30, 60 or 100 tablets.

#### Marketing Authorisation Holder

Torrent Pharma (UK) Ltd.  
Unit 4, Charlwood Court,  
County Oak Way  
Crawley  
West Sussex. RH11 7XA  
United Kingdom

#### Manufacturer

Torrent Pharma (UK) Ltd.  
Unit 4, Charlwood Court,  
County Oak Way  
Crawley  
West Sussex. RH11 7XA  
United Kingdom

This leaflet was last revised in 12/2012

#### Pramipexole tablets

Pramipexole tablets 0.088mg	PL36687/0014
Pramipexole tablets 0.18mg	PL36687/0015
Pramipexole tablets 0.35mg	PL36687/0016
Pramipexole tablets 0.7mg	PL36687/0017

LOCATION : Indrad	COUNTRY : UK	Supersedes A/W No.:		
SIZE : 180 x 460 mm_Front/Back Side	CODE : 8038428-7803	DATE : 20-12-2012		
REMARK : Folding Length 35 mm				
SUBSTRATE :				
Activities	Department	Name	Signature	Date
Prepared By	Pkg.Dev			
Reviewed By	Pkg.Dev			
Reviewed By	RA			
Approved By	CQA			
<b>This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.</b>				

