

RAMIPEX TABLETS

Pramipexole dihydrochloride monohydrate (0.125mg, 0.25mg)

What is in this leaflet

1. What is RAMIPEX used for
2. How RAMIPEX works
3. Before you use RAMIPEX
4. How to use RAMIPEX
5. While you are using it
6. Side effects
7. Storage and Disposal of RAMIPEX
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What RAMIPEX is used for

RAMIPEX is used as:

- a. Treatment of Parkinson's disease. It can be used alone or in combination with levodopa (another medicine for Parkinson's disease).
- b. Treatment of idiopathic restless legs syndrome (a common condition of the nervous system that causes an overwhelming, irresistible urge to move the legs).

How RAMIPEX works

RAMIPEX 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.

Before you use RAMIPEX

- When you must not use it

Do not take RAMIPEX if you are allergic to pramipexole or to any of the other ingredients of this medicine

RAMIPEX is not recommended for use in children or adolescent under 18 years.

Pregnancy and lactation

Do not take RAMIPEX if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take RAMIPEX if you are breast-feeding. Ask your doctor or

pharmacist for advice before taking any medicine.

- Before you start use it

Talk to your doctor before taking RAMIPEX. 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 RAMIPEX.
- Dystonia (inability of keeping your body and neck straight and upright (axial dystonia)). In particular, you may experience forward flexion of the head and neck (also called antecollis), forward bending of the lower back (also called camptocormia) or sideways bending of the back (also called pleurothotonus or Pisa Syndrome).
- Sleepiness and episodes of suddenly falling asleep.
- Psychosis (eg. Comparable with symptoms of schizophrenia such as withdrawal from reality, illogical patterns of thinking, delirious and hallucinations).
- Vision impairment. You should have regular eye examinations during treatment with RAMIPEX.
- 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 or loss of reality). 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 RAMIPEX treatment. If the problems persist more than a few weeks, your doctor may need to adjust your treatment.

Tell your doctor if you are developing an inability of keeping your body and neck straight and upright (axial dystonia). If this happens, your doctor may want to adjust or change your medication.

- Taking other medicines

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.

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).

RAMIPEX TABLETS

Pramipexole dihydrochloride monohydrate (0.125mg, 0.25mg)

- 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).
- Levodopa (to treat Parkinson's disease).

If you are taking levodopa, the dose of levodopa is recommended to be reduced when you start treatment with RAMIPEX.

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

How to use RAMIPEX

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.

- How much to use

Parkinson's disease

- The daily dose is to be taken divided into 3 equal doses.
- During the first week, the usual dose is 0.375mg per day and increased every 5-7 days as directed by your doctor until your symptoms are controlled (maintenance dose).

Ascending-Dose Schedule of RAMIPEX		
Week	Dosage (mg)	Total Daily Dose (mg)
1	3 x 0.125	0.375
2	3 x 0.25	0.75
3	3 x 0.5	1.50

▪ **Maintenance treatment:**

- The individual dose should be in the range of 0.375mg to a maximum of 4.5mg per day.

Restless legs syndrome:

- The recommended starting dose of RAMIPEX is 0.125mg taken once daily 2-3 hours before bedtime. For patients requiring additional symptomatic relief, the dose may be increased every 4-7 days to a maximum of 0.75mg per day (as shown in the table below)

Ascending-Dose Schedule of RAMIPEX	
Titration Step	Once Daily Evening Dose (mg)
1	0.125
2*	0.25
3*	0.50
4*	0.75
* if needed	

If you stop taking your tablets for more than a few days and want to restart the treatment, you must start again at the lowest dose. You can then build up the dose again, as you did the first time. Ask your doctor for advice.

Your doctor will review your treatment after 3 months to decide whether or not to continue the treatment.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking RAMIPEX for as long as your doctor recommends.

- If you forget to use it

It is important to take your RAMIPEX tablet regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there

are no signs of discomfort or poisoning. You may need urgent medical attention.

You may experience vomiting, restlessness, or any of the side effects as described in section "Side Effects".

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking RAMIPEX.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking your medicine unless your doctor tells you to.
- Do not take any new medicines without consulting your doctor.
- Do not give RAMIPEX to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Patients being treated with RAMIPEX and presenting with somnolence and/or sudden sleep episodes must be informed to refrain from driving or engaging in activities where impaired alertness may put themselves or others at risk of serious injury or death (e.g. operating machines) until such recurrent episodes and somnolence have resolved.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very common side effects include:

- Dizziness
- Sleepiness
- Dyskinesia (abnormal, uncontrolled movement of the limbs)

RAMIPEX TABLETS

Pramipexole dihydrochloride monohydrate (0.125mg, 0.25mg)

- Nausea

Common side effects:

- Insomnia
- Hallucinations
- Abnormal dreams
- Confusion
- Impulse control disorders (eg: increased gambling, libido, hypersexuality, compulsive spending or buying, binge and compulsive eating)
- Headache
- Visual impairment
- Blurred or reduced visual
- Low blood pressure
- Constipation
- Vomiting
- Tiredness
- Peripheral edema (accumulation of excessive amounts of fluid especially in hands and legs)
- Weight decrease including decreased appetite

Uncommon side effects:

- Lung infection
- Inappropriate hormone secretion
- Compulsive shopping
- Increased gambling
- Restlessness
- Hypersexuality
- Delusion
- Libido disorder
- Paranoia
- Binge eating
- Delirium
- Sudden onset of sleep
- Amnesia (loss or impairment of memory)
- Muscle spasm
- Sudden loss of consciousness
- Heart failure
- Allergic, itchiness, rash
- Increased weight
- Difficulty breathing

Other side effects:

- Mania (mental illness marked by periods of great excitement or euphoria, delusions, and overactivity)
- Anxiety
- Depression
- Sweating
- Pain

- Lack of interest, enthusiasm, or concern.

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

Tell your doctor if you get any side effect that bothers you or that does not go away.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Torleva

- Storage

- Store below 30°C. Keep medicines out of reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

RAMIPEX 0.125mg TABLET:

White to off white, round, flat, bevel edged, uncoated tablets, debossed with "P1" on one side and plain on other side.

RAMIPEX 0.25 mg TABLET:

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 the other side.

- Ingredients

Active ingredient:

- Pramipexole dihydrochloride monohydrate equivalent to Pramipexole base.

Inactive ingredients:

- Mannitol 25.

- Starch (Maize starch).
- Silica colloidal anhydrous.
- Pregelatinized starch.
- Povidone K-30.
- Purified water.
- Magnesium stearate.

Packing: Pramipexole Dihydrochloride Monohydrate Tablets 0.125mg & 0.25mg are packed in Alu-Alu blister of 10 tablets. 3 and 10 blisters are packed in a carton box with package leaflet. Not all presentation may be available locally.

- MAL number(s):

RAMIPEX 0.125mg TABLET:
MALXXXXXXXXXX

RAMIPEX 0.25 mg TABLET:
MALXXXXXXXXXX

Manufacturer

Torrent Pharmaceuticals Ltd.
Near Indrad Village, Taluka Kadi,
District Mehsana Gujarat 382721
India

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn. Bhd.
Suite E-08-08 Plaza Mont Kiara,
No. 2 Jalan Kiara Mont Kiara,
50480 Kuala Lumpur,
Malaysia.

Date of revision

15/06/2021

Serial Number

NPRA (R2) 20/079