Pramipexole 0.088 mg tablets

1. What Pramipexole is and what it is used for

Pramipexole contains the active substance pramipexole and becomes a medicine containing known as dopamine agonist, which stimulates 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 Parkinson's disease.
- treat restless legs syndrome.
- treat symptoms of some movement disorders, such as those associated with Parkinson's disease.

2. What you need to know before you take Pramipexole

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

3. How to take Pramipexole

Always take this medicine exactly as your doctor or pharmacist has told you. If you forget to take Pramipexole that you have to stop taking Pramipexole.

4. Possible side effects

Pramipexole may be authorised to treat other conditions. This will be increased every 5 – 7 days as directed. If the treatment with Pramipexole.

5. How to store Pramipexole

- Store below 25°C.
- Keep the bottle tight after opening.
- Do not use after the expiry date on the bottle.

Pramipexole can be taken with or without food.

5. Pregnancy and breast-feeding

Pramipexole can cause hallucinations (seeing, hearing or feeling things that are not there).

There is no information available about the safety of Pramipexole use before you have taken Pramipexole.

6. Effects of taking too much

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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 dopaminergic rebound syndrome which may include a major health risk. The symptoms which may include:
- akinesia (loss of muscle movement)
- rigidity
- dystonia
- eye movement disorder
- akathisia
- uncontrolled movements (e.g. coma).
If you stop or reduce Pramipexole you may also develop a medical condition called withdrawal syndrome. The symptoms include dyskinesia, anxiety, agitation, sweating or pan in. If you experience these symptoms you should stop Pramipexole.
If you have any further questions on the use of this medicine, and also if symptoms persist, tell your doctor.

4. Possible side effects

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

Evaluation of these side effects is based on the following frequencies:

Very common: This side effect affects more than 1 in 10 people

Common: This side effect affects more than 1 in 10 people but less than 1 in 100 people

Uncommon: This side effect affects less than 1 in 100 people but more than 1 in 1,000 people

Rare: This side effect affects less than 1 in 1,000 people

Very rare: This side effect affects less than 1 in 10,000 people

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)
- Sleeplessness
- Dizziness
- Nausea (vomiting)

Common:
- Hallucinations (seeing, hearing or feeling things that are not there)
- Confusion
- Tachycardia (heart rate faster than usual)
- Insomnia
- Headache
- Tiredness (fatigue)
- Dizziness
- Abnormal dreams
- Constipation
- Visual impairment
- Stomach ache (abdominal pain)
- Weight loss due to decreased appetite
- Palpitations
- Dryness (diffficulty inhaling)
- Mania (agitation, feeling elated or over-excited)

Uncommon:
- Delirium (decreased awareness, confusion, loss of reality)
- Binge eating (eating large amounts of food in a short time period)
- Dizziness
- Fainting
- Excess of fluid, usually in the legs (peripheral oedema)
- Confusion
- Dysphonia (difficulty in breathing)
- Confusion
- Pneumonia (infection of the lungs)
- P.ruption (scars or blisters)
- Visual impairment
- Constipation
- Abnormal dreams
- Hypotension (low blood pressure)

Not known: These side effects cannot be estimated from the available data.

Reporting of side effects
If you or any other member of your family or friends experience any of these behaviors, they will discuss ways of managing or reducing the symptoms.

For the side effects marked with a “*,” frequency cannot be estimated from the available data, 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.”

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

Pramipexole may also cause the following side effects:

Common:
- Nausea (sickness)
- Fever (which can cause shortness of breath or ankle swelling)*
- Inappropriate antidiuretic hormone secretion*
- Pneumonia (infection of the lungs)*
- Hyperkinesia (increased movements and inability to keep still)*
- Pneumonia (infection of the lungs)*
- P.ruption (scars or blisters)*
- Amnesia (memory disturbance)*
- Hypersensitivity

Other side effects include:
- Fainting
- Confusion
- Tachycardia (heart rate faster than usual)
- Fever (which can cause shortness of breath or ankle swelling)*
- Inappropriate antidiuretic hormone secretion*
- Pneumonia (infection of the lungs)*
- Hyperkinesia (increased movements and inability to keep still)*
- P.ruption (scars or blisters)*
- Amnesia (memory disturbance)*
- Hypersensitivity

These side effects are not there)

Keep the medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister pack after the EXP. The expiry date refers to the last day of that month.

Do not throw away any medicine via wastewater or household waste. Always throw away medicines you no longer use. These medicines might harm people or cause pollution to the environment.

5. How to store Pramipexole

This medicine is supplied as tablets.

6. Contents of the pack and other information

What Pramipexole contains

Each tablet contains 0.25 mg of pramipexole dihydrochloride monohydrate equivalent to 0.125 mg of pramipexole.

Each tablet contains 0.125 mg of pramipexole dihydrochloride monohydrate equivalent to 0.25 mg of pramipexole.

Each tablet contains 0.088 mg of pramipexole dihydrochloride monohydrate equivalent to 0.175 mg of pramipexole.

The other ingredients are: Mannitol (E421), hydroxypropyl cellulose, povidone K90, ethylcellulose, magnesium stearate.

What Pramipexole looks like and contains of the pack

Tablet:

Pramipexole 0.088 mg Tablets:

White to off-white, beveled edge, uncoated tablets, debossed with “Y” on one side and “41” on the other side

Pramipexole 0.125 mg Tablets:

White to off-white, beveled edge, uncoated tablets, debossed with “Y” and “42” separated by score line on one side and plain with score line on other side

The tablets are supplied in blisters packed into unit dose foil packages.

Pramipexole 0.175 mg Tablets:

White to off-white, beveled edge, uncoated tablets, debossed with “Y” and “45” separated by score line on one side and plain with score line on other side

The tablets are supplied in blisters packed into unit dose foil packages.

Pramipexole tablets are available in Polyethylene-Aluminium foil blister packs. The blisters are designed with press-in device allowing entry to the foil pack containing tablet.

Pramipexole tablet:

Pramipexole 0.088 mg Tablets:

White to off-white, beveled edge, uncoated tablets, debossed with “Y” and “41” separated by score line on one side and plain with score line on other side

The tablets are supplied in polyethylene foil packs.

The tablets are supplied in Polyethylene-Aluminium foil blister packs. The blisters are designed with press-in device allowing entry to the foil pack containing tablet.

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