Package leaflet: Information for the patient

Pramipexole Viatris 0.26 mg prolonged-release tablets
Pramipexole Viatris 0.52 mg prolonged-release tablets
Pramipexole Viatris 1.05 mg prolonged-release tablets
Pramipexole Viatris 1.57 mg prolonged-release tablets
Pramipexole Viatris 2.1 mg prolonged-release tablets
Pramipexole Viatris 2.62 mg prolonged-release tablets
Pramipexole Viatris 3.15 mg prolonged-release 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 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 Viatris is and what it is used for
2. What you need to know before you take Pramipexole Viatris
3. How to take Pramipexole Viatris
4. Possible side effects
5. How to store Pramipexole Viatris
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1. What Pramipexole Viatris is and what it is used for

Pramipexole Viatris contains the active substance pramipexole, which 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 Viatris 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 Viatris

Do not take Pramipexole Viatris:
- if you are allergic to pramipexole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Pramipexole Viatris

Tell your doctor if you have or have had any other medical conditions, especially any of the following:
- Problems with your kidneys.
- Psychosis (e.g. comparable with symptoms of schizophrenia).

- 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, which can make you dizzy or lose consciousness).

You should also tell your doctor if you develop any of the above conditions during your treatment with Pramipexole Viatris, as well as the following:
- 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 uptitration of Pramipexole Viatris.
- 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 sidewards bending of the back (also called pleurothotonus or Pisa Syndrome). If this happens, your doctor may want to change your medication.
- Sleepiness and episodes of suddenly falling asleep (see also “Driving and using machines” in this section).
- Changes in your vision. You should have regular eye examinations during treatment with Pramipexole Viatris.

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 notice 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.**

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your Pramipexole Viatris treatment. If the problems persist more than a few weeks, your doctor may need to adjust your treatment.

Pramipexole Viatris prolonged-release tablet is a specially designed tablet from which the active ingredient is gradually released, once the tablet has been ingested. Parts of tablets may occasionally be passed and seen in the stool (faeces) and may look like whole tablets. Inform your doctor if you find tablet pieces in your faeces.

Children and adolescents

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

Other medicines and Pramipexole Viatris
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 Viatris together with antipsychotic medicines (to treat mental health conditions).

Take care if you are taking the following medicines:
- cimetidine (to treat excess stomach acid and stomach ulcers);

- amantadine (to treat Parkinson's disease);
- mexiletine (to treat irregular heartbeats, a condition known as ventricular arrhythmia);
- zidovudine (to treat HIV infection);
- 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).
- any medicines that calm you down (have a sedative effect).

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

Pramipexole Viatris with food, drink and alcohol

You should be cautious while drinking alcohol during treatment with Pramipexole Viatris, as alcohol can increase the risk of sleepiness and suddenly falling asleep. Pramipexole Viatris 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 Viatris.

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

Breast-feeding
Pramipexole Viatris should not be used during breast-feeding. Pramipexole can reduce the production of breast milk. Also, it may pass into the breast milk and could reach your baby. If use of Pramipexole Viatris 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 when taken with alcohol or other medicines with a sedative effect. 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 Viatris

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

Take Pramipexole Viatris prolonged-release tablets only once a day and each day at about the same time.
You can take Pramipexole Viatris with or without food. Swallow the tablets whole with water.

Do not chew, divide or crush the prolonged-release tablets. If you do, there is a danger you could overdose, because the medicine may be released into your body too quickly.

During the first week, the recommended daily dose is 0.26 mg pramipexole. The dose will be increased every 5-7 days as directed by your doctor until your symptoms are controlled (maintenance dose).

Ascending dose schedule of Pramipexole Viatris prolonged-release tablets		
Week	Daily dose (mg)	Number of tablets
1	0.26	One Pramipexole Viatris 0.26 mg prolonged-release tablet.
2	0.52	One Pramipexole Viatris 0.52 mg prolonged-release tablet, OR two Pramipexole Viatris 0.26 mg prolonged-release tablets.
3	1.05	One Pramipexole Viatris 1.05 mg prolonged-release tablet, OR two Pramipexole Viatris 0.52 mg prolonged-release tablets, OR four Pramipexole Viatris 0.26 mg prolonged-release tablets.

The recommended maintenance dose is 1.05 mg per day. However, your dose may have to be increased even further. If necessary, your doctor may increase your dose up to a maximum of 3.15 mg of pramipexole a day. A lower maintenance dose of one Pramipexole Viatris 0.26 mg prolonged-release tablet a day is also possible.

Patients with kidney disease
If you have kidney disease, your doctor may advise you to take the usual starting dose of 0.26 mg prolonged-release tablets only every other day for the first week. After that, your doctor may increase the dosing frequency to one 0.26 mg prolonged-release tablet every day. If a further dose increase is necessary, your doctor may adjust it in steps of 0.26 mg pramipexole up to a maximum of 1.57 mg a day.

If you have serious kidney problems, your doctor may need to switch you to a different pramipexole medicine. If during treatment your kidney problems get worse, you should contact your doctor as soon as possible.

If you are switching from pramipexole immediate release tablets
Your doctor will base your dose of Pramipexole Viatris prolonged-release tablets on the dose of immediate release tablets you were taking.

Take your immediate release tablets as normal the day before you switch. Then take your Pramipexole Viatris prolonged-release tablets next morning and continue taking it as recommended, and do not take any more pramipexole immediate release tablets.

If you take more Pramipexole Viatris than you should
If you accidentally take too many tablets,
- Contact your doctor or nearest hospital casualty department immediately for advice.
- You may feel or be sick, feel restless or agitated, or experience low blood pressure, hallucinations or any of the side effects as described in section 4, “Possible side effects”.

If you forget to take Pramipexole Viatris

If you forget to take a dose of Pramipexole Viatris, but remember within 12 hours of your usual time, take your dose straight away and then take your next dose at the usual time. If you forget for more than 12 hours, simply take the next single dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Pramipexole Viatris
Do not stop taking Pramipexole Viatris 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.

You should not stop treatment with Pramipexole Viatris 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 (akinesia),
- rigid muscles,
- fever,
- unstable blood pressure,
- increased heart rate (tachycardia)
- confusion,
- depressed level of consciousness (e.g. coma).

If you stop or reduce Pramipexole Viatris you may also develop a medical condition called dopamine agonist withdrawal syndrome. The symptoms include depression, apathy, anxiety, fatigue, sweating or pain. If you experience these symptoms you should contact your physician.

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.

Contact a doctor IMMEDIATELY if you experience any of the following side effects:
- Signs of a serious allergic reaction, including sudden wheezing, rash, itching or hives on the skin, swelling of the lips, tongue, face or throat causing difficulties swallowing or breathing (uncommon side effect).
- Pneumonia, an infection of the lungs that can cause fever, shivering, sweating, difficulty breathing, chest pain and feeling generally unwell (uncommon side effect).
- Heart failure, which can cause shortness of breath or a persistent cough, extreme tiredness and swelling of the ankles* (uncommon side effect).
- A lower than normal level of sodium in the blood, which may make you feel weak and confused with aching of muscles. This may be due to inappropriate antidiuretic hormone (ADH) secretion, a hormone that causes the body to retain water and dilute the blood, reducing the amount of sodium* (uncommon side effect).
- Fainting (uncommon side effect).

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

Other possible side effects:

Very common (may affect more than 1 in 10 people):
- Abnormal, uncontrolled movements of the limbs (dyskinesia),

- Sleepiness,
- Dizziness,
- Feeling sick (nausea).

Common (may affect up to 1 in 10 people):
- Seeing, hearing or feeling things that are not there (hallucinations),
- Confusion,
- Tiredness (fatigue),
- Sleeplessness (insomnia),
- Excess of fluid, usually in the legs (peripheral oedema),
- Headache,
- Low blood pressure (hypotension),
- Abnormal dreams,
- Constipation,
- Problems with your vision such as blurred, double or reduced clarity of vision,
- Being sick (vomiting),
- Weight loss including decreased appetite.

Uncommon (may affect up to 1 in 100 people):
- Excessive fear for one's own well-being (paranoia),
- Delusion,
- Suddenly falling asleep,
- Memory disturbance (amnesia),
- Increased movements and inability to keep still (hyperkinesia),
- Weight increase,
- Rash,
- Itching,
- Restlessness,
- Shortness of breath (dyspnoea),
- Hiccups.
- 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).
- Decreased awareness, confusion, loss of reality (delirium).

Rare (may affect up to 1 in 1000 people)
- Feeling agitated, elated or over-excited (mania)
- Spontaneous penile erection

Not known (Frequency cannot be estimated from the available data):
- After stopping or reducing your Pramipexole Viatris treatment: Depression, apathy, anxiety, fatigue, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS).

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".

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pramipexole Viatris

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

This medicine does not require any special temperature storage condition. Store in the original package in order to protect from moisture.

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 Viatris contains

The active substance is pramipexole.

Each tablet contains 0.375 mg pramipexole dihydrochloride monohydrate equivalent to 0.26 mg pramipexole.
Each tablet contains 0.75 mg pramipexole dihydrochloride monohydrate equivalent to 0.52 mg pramipexole.
Each tablet contains 1.5 mg pramipexole dihydrochloride monohydrate equivalent to 1.05 mg pramipexole.
Each tablet contains 2.25 mg pramipexole dihydrochloride monohydrate equivalent to 1.57 mg pramipexole.
Each tablet contains 3 mg pramipexole dihydrochloride monohydrate equivalent to 2.1 mg pramipexole.
Each tablet contains 3.75 mg pramipexole dihydrochloride monohydrate equivalent to 2.62 mg pramipexole.
Each tablet contains 4.5 mg pramipexole dihydrochloride monohydrate equivalent to 3.15 mg pramipexole.

The other ingredients are hypromellose 2208 (E464), pregelatinised starch (maize), colloidal anhydrous silica, magnesium stearate (E470b).

What Pramipexole Viatris looks like and contents of the pack

Pramipexole Viatris 0.26 mg prolonged-release tablets	:	White to off-white, round, beveled edge tablets, of approximately 8.9 mm of diameter x 3.6 mm of thickness and marked “PP1” on one side of the tablet and “M” on other side.
Pramipexole Viatris 0.52 mg prolonged-release tablets	:	White to off-white, round, beveled edge tablets, of approximately 9.9 mm of diameter x 4.0 mm of thickness and marked “PP2” on one side of the tablet and “M” on other side.
Pramipexole Viatris 1.05 mg prolonged-release tablets	:	White to off-white, oval shaped, biconvex tablets, with dimensions of approximately 13.9 mm x 6.7 mm x 4.85 mm and marked “PP3” on one side of the tablet and “M” on other side.
Pramipexole Viatris 1.57 mg prolonged-release tablets	:	White to off-white, oval shaped, biconvex tablets, with dimensions of approximately 14.9 mm x 6.9 mm x 5.15 mm and marked “PP4” on one side of the tablet and “M” on other side.
Pramipexole Viatris 2.1 mg prolonged-release tablets	:	White to off-white, oval shaped, biconvex tablets, with dimensions of approximately 14.9 mm x 6.9 mm x 5.35 mm and marked “PP5” on one side of the tablet and “M” on other side.
Pramipexole Viatris 2.62 mg prolonged-release tablets	:	White to off-white, oval shaped, biconvex tablets, with dimensions of approximately 16.1 mm x 7.9 mm x 4.85 mm and marked “PP6” on one side of the tablet and “M” on other side.
Pramipexole Viatris 3.15 mg prolonged-release tablets	:	White to off-white, oval shaped, biconvex tablets, with dimensions of approximately 16.1 mm x 7.9 mm x 5.35 mm and marked “PP7” on one side of the tablet and “M” on other side.

Pramipexole Viatris is available in blister packs of 7, 10, 30, 90 and 100 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturers

Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary.

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