PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Pexola® ER 0,375 mg extended release tablets
Pexola® ER 0,75 mg extended release tablets
Pexola® ER 1,5 mg extended release tablets
Pexola® ER 3,0 mg extended release tablets

Pramipexole dihydrochloride monohydrate

Read all of this leaflet carefully before you start taking PEXOLA ER.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- PEXOLA ER has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT PEXOLA ER EXTENDED RELEASE TABLETS CONTAIN

- The active substance is pramipexole dihydrochloride monohydrate.

Each PEXOLA ER 0,375 mg extended release tablet contains pramipexole dihydrochloride monohydrate 0,375 mg.
Each PEXOLA ER 0,75 mg extended release tablet contains pramipexole dihydrochloride monohydrate 0,75 mg.
Each PEXOLA ER 1,5 mg extended release tablet contains pramipexole dihydrochloride monohydrate 1,5 mg.
Each PEXOLA ER 3,0 mg extended release tablet contains pramipexole dihydrochloride monohydrate 3,0 mg.

- The other ingredients are anhydrous colloidal silica, carbomer, magnesium stearate, maize starch and hypromellose.

Sugar free.

2. WHAT PEXOLA ER EXTENDED RELEASE TABLETS ARE USED FOR

PEXOLA ER extended release tablets are used to treat the symptoms of Parkinson's disease either alone or in combination with levodopa.

3. BEFORE YOU TAKE PEXOLA ER EXTENDED RELEASE TABLETS

Do not take PEXOLA ER:

- if you are hypersensitive (allergic) to pramipexole or any of the other ingredients of PEXOLA ER tablets
- if you are under the age of 18 years
- if you have moderate to severe kidney (renal) problems.

Take special care with PEXOLA ER:

- PEXOLA ER may cause drowsiness and episodes of suddenly falling asleep, sometimes without warning. Be cautious about drinking alcohol as this may worsen the drowsiness. Ask your doctor or pharmacist whether any other medicines you are taking can cause drowsiness as the combination of these medicines with PEXOLA ER can lead to severe drowsiness.
- PEXOLA ER may cause a lowering of your blood pressure especially at the beginning of treatment. This can result in symptoms like dizziness, nausea, fainting and sometimes, sweating. Consequently, you should avoid rising rapidly after sitting or lying down, especially if you have been doing so for long periods. You will need to have your blood pressure checked regularly.
- PEXOLA ER may affect your ability to drive and use machines because of hallucinations, drowsiness and falling asleep during the day. Please refer to "**Driving and using machinery**".
- Studies of people with Parkinson's disease show that they may be at an increased risk of developing melanoma, a form of skin cancer, when compared to people without Parkinson's disease. It is not known whether skin cancer is associated with PEXOLA ER use. Therefore if you are being treated with PEXOLA ER you should have periodic skin examinations.

Tell your doctor and pharmacist if you have or develop any medical conditions or symptoms especially any of the following:

- kidney, heart or blood pressure problems.
- behavioural changes (e.g. pathological gambling, compulsive shopping), increased libido (e.g. increased sexual desire), binge eating or abnormal compulsive behaviour.
- confusion and hallucinations (seeing, hearing or feeling things that are not there).
- dyskinesia (e.g. abnormal, uncontrolled movements of the limbs). If you have Parkinson's disease and are also taking levodopa, you might develop dyskinesia during up titration of PEXOLA ER.
- sleepiness or episodes of suddenly falling asleep.
- vision impairment. You should have regular eye examinations during treatment with PEXOLA ER.

Tell your doctor if you or your family/caregiver notice that you are developing addiction-like symptoms resulting in a strong craving for high doses of PEXOLA ER and other medicines that are used to treat Parkinson's disease (known as dopamine dysregulation syndrome).

Taking PEXOLA ER with food and drink:

- Drinking alcohol may worsen the drowsiness caused by PEXOLA ER.

- Take PEXOLA ER tablets with water, with or without food.

Pregnancy and breastfeeding:

The effect of PEXOLA ER on the unborn child is not known. Therefore, do not take PEXOLA ER if you are pregnant.

PEXOLA ER should not be used during breastfeeding.

If you are pregnant, think you might be pregnant or if you intend to become pregnant while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

PEXOLA ER can cause hallucinations (seeing, hearing or feeling things that are not there). You should be aware that this may affect your ability to drive or use machinery.

PEXOLA ER has also been associated with sleepiness and episodes of suddenly falling asleep. If you experience these side effects, you must not drive or operate machinery. You should tell your doctor if this occurs.

Taking other medicines with PEXOLA ER:

If you are taking other medicines on a regular basis, including medicines bought over the counter and complementary or traditional medicines, the use of PEXOLA ER with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

PEXOLA ER can interfere with some other medicines such as:

- cimetidine and ranitidine (used to treat excess stomach acid and stomach ulcers)
- amantadine (used to treat Parkinson's disease)
- diltiazem, triamterene, verapamil, quinidine (used for cardiovascular conditions).

You should avoid taking PEXOLA ER together with antipsychotic medicines (used for mood or mental illness) or metoclopramide (used for nausea and other gastrointestinal conditions). Please consult your doctor, pharmacist or other healthcare professional for advice.

If you are also taking levodopa-containing medication for your Parkinson's disease, your doctor may reduce your dose of levodopa after you started treatment with PEXOLA ER.

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

It is best to ask your doctor or pharmacist for advice before you start taking any other medicine.

4. HOW TO TAKE PEXOLA ER EXTENDED RELEASE TABLETS

Take PEXOLA ER extended release tablets exactly as your doctor has told you. Your doctor will advise you on the right dosing.

Do not take more or less tablets and do not take them more often than recommended. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of PEXOLA ER is too strong or too weak, talk to your doctor or pharmacist.

- The usual dosage schedule is shown below. Your doctor will slowly (every 7 days) change the dose of PEXOLA ER until PEXOLA ER controls your symptoms.
- Take PEXOLA ER tablets only once a day. Take the tablets each day at about the same time.
- Swallow the tablets whole with water. Do not chew, divide or crush PEXOLA ER tablets. If you do, there is a danger you could overdose, because the medicine may be released into your body too quickly.

Usual adult ascending-dose schedule for PEXOLA ER Extended Release tablets in Parkinson's disease	
Week 1:	PEXOLA ER 0,375 mg taken once a day
Week 2:	PEXOLA ER 0,75 mg taken once a day
Week 3:	PEXOLA ER 1,5 mg taken once a day

- If needed, your doctor may increase the daily dose by 0,75 mg every week up to a maximum dose of 4,5 mg per day.
- If you develop kidney problems, or 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 to PEXOLA ER extended release tablets:
Your doctor will base your dose of PEXOLA ER tablets on the dose of pramipexole immediate release tablets you were taking.
Take your pramipexole immediate release tablets as normal the day before you switch. Then take your PEXOLA ER tablets the next morning and do not take any more pramipexole immediate release tablets.

If you take more PEXOLA ER than you should:

Overdosage could cause adverse effects including nausea, vomiting, restlessness, hallucinations, agitation and fainting.
In the event of overdosage or accidental intake, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take PEXOLA ER:

If you forget to take a dose of PEXOLA ER, but remember within 12 hours of your usual time, take your tablet straight away and then take your next tablet 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 dose.

Effects when treatment with PEXOLA ER is stopped:

Do not stop taking PEXOLA ER without first talking to your doctor.
If you have to stop taking this medicine your doctor will want you to slowly lower the dose over several days before you stop taking this medicine completely. This reduces the risk of worsening symptoms.

You should not stop treatment with PEXOLA ER 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.

5. POSSIBLE SIDE EFFECTS

PEXOLA ER extended release tablets can cause side effects.

Frequent side effects are:

- sleepiness
- nausea (feeling sick)
- abnormal behaviour (urge to behave in an unusual way e.g. compulsion to gamble, shop or binge eat; or increased sexual desire)
- sleeplessness (insomnia)
- hallucinations (seeing, hearing or feeling things that are not there)
- headache
- dizziness
- dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- visual impairment (e.g. blurred vision, double vision or reduction in sharpness of vision)
- hypotension (low blood pressure)
- constipation
- vomiting (being sick)
- fluid accumulation (swelling from fluid), usually in the legs (peripheral oedema)
- tiredness (fatigue)
- weight loss including decreased appetite

- falling asleep during activities of daily living.

There have been reports of patients taking PEXOLA ER to treat Parkinson's disease that reported problems with gambling, compulsive eating, compulsive shopping, and increased sex drive. If you or your family members notice that you are developing unusual behaviour, talk to your doctor.

Dopamine dysregulation syndrome: strong craving for high doses of PEXOLA ER that are much higher than the doses needed to control your movement symptoms adequately, known as dopamine dysregulation syndrome. Some patients experience unusually severe involuntary movements (dyskinesia), mood swings, or other side effects after taking high doses of PEXOLA ER.

Not all side effects reported for PEXOLA ER are included in this leaflet. Should your general health worsen while taking PEXOLA ER, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF PEXOLA ER EXTENDED RELEASE TABLETS

Store PEXOLA ER extended release tablets in a dry and cool place (at or below 30 °C).
Keep PEXOLA ER extended release tablets in the original blister pack until needed.

Keep all medicines out of the reach and sight of children.

Do not take this medicine after the expiry date stated on the blister strips and carton.
Return unused or expired medicines to your pharmacist for safe disposal.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF PEXOLA ER EXTENDED RELEASE TABLETS

Cartons containing 30 tablets packed in silver aluminium blister strips of 10 tablets per strip.

8. IDENTIFICATION OF PEXOLA ER EXTENDED RELEASE TABLETS

PEXOLA ER 0,375 mg extended release tablets: White to off white, round, biconvex, bevel-edged tablets. One side is debossed with the code P1, the other side is debossed with the Boehringer Ingelheim company symbol.
PEXOLA ER 0,75 mg extended release tablets: White to off white, round, biconvex, bevel-edged tablets. One side is debossed with the code P2, the other side is debossed with the Boehringer Ingelheim company symbol.
PEXOLA ER 1,5 mg extended release tablets: White to off white, oval, biconvex tablets. One side is debossed with the code P3, the other side is debossed with the Boehringer Ingelheim company symbol.
PEXOLA ER 3,0 mg extended release tablets: White to off white, oval, biconvex tablets. One side is debossed with the code P4, the other side is debossed with the Boehringer Ingelheim company symbol.

9. REGISTRATION NUMBERS

PEXOLA ER 0,375 mg extended release tablets: 43/5.4.1/1062
PEXOLA ER 0,75 mg extended release tablets: 43/5.4.1/1063
PEXOLA ER 1,5 mg extended release tablets: 43/5.4.1/1064
PEXOLA ER 3,0 mg extended release tablets: 43/5.4.1/1065

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Ingelheim Pharmaceuticals (Pty) Ltd
Suite 1, Building 4, 2nd Floor
Waterfall Corporate Campus
74 Waterfall Drive
Midrand
South Africa
Tel. No.: +27 (011) 348 2400

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration: 7 December 2012
Revised: 25 January 2023

CCDS: 0186-14