APPROVED PIL:

PATIENT INFORMATION LEAFLET _____

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- PEXOLA 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.

SCHEDULING STATUS **S4** ABCD

Pexola® 0,125 mg; 0,25 mg; 1,0 mg tablets

Pramipexole dihydrochloride monohydrate

1. WHAT PEXOLA TABLETS CONTAIN

- The active substance is pramipexole dihydrochloride monohydrate

  Each PEXOLA 0,125 mg tablet contains pramipexole dihydrochloride monohydrate 0,125 mg
  Each PEXOLA 0,25 mg tablet contains pramipexole dihydrochloride monohydrate 0,25 mg
  Each PEXOLA 1,0 mg tablet contains pramipexole dihydrochloride monohydrate 1,0 mg

- The other ingredients are anhydrous colloidal silica, magnesium stearate, maize starch, mannitol and povidone.

2. WHAT PEXOLA TABLETS ARE USED FOR

PEXOLA 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.

PEXOLA is used to:

- treat the symptoms of Parkinson's disease. It can be used alone or in combination with levodopa.
- treat the symptoms of Restless Legs Syndrome (RLS).

3. BEFORE YOU TAKE PEXOLA

Do not take PEXOLA:

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

Take special care with PEXOLA:

- PEXOLA 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 can lead to severe drowsiness**.**

- PEXOLA 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, especially at the beginning of treatment.
- PEXOLA 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 use. Therefore if you are being treated with PEXOLA 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. inability to control the urge to gamble, spend money inappropriately, binge eat as well as increased sexual desire which may be inappropriate.
- confusion and hallucinations (seeing, hearing or feeling things that are not there).
- 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 up titration of PEXOLA.
- sleepiness or episodes of suddenly falling asleep.
- vision impairment (e.g. blurred vision or reduction in sharpness of vision). You should have regular eye examinations during treatment with PEXOLA.
- augmentation in Restless Legs Syndrome (RLS) (symptoms that start earlier in the day than usual, are more intense and involve other limbs).

Taking PEXOLA with food and drink:

- Be cautious about drinking alcohol as this may worsen the drowsiness.
- Take PEXOLA tablets with water, with or without food. If nausea occurs, take PEXOLA tablets with food, which helps to lessen nausea.

Pregnancy and breastfeeding:

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

PEXOLA should not be used during breastfeeding. PEXOLA can reduce the production of breast milk. If the use of PEXOLA is unavoidable, breastfeeding should be stopped.

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

Driving and using machinery:

PEXOLA 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 has also 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.

Important information about some of the ingredients of PEXOLA tablets:
PEXOLA tablets contain mannitol. This may have a mild laxative (bowel loosening) effect.

Taking other medicines with PEXOLA:
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 with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

PEXOLA can interfere with some other medicines such as:
- cimetidine and ranitidine (used to treat excess stomach acid and stomach ulcers)
- amantadine (which can be used to treat Parkinson's disease)
- diltiazem, triamterene, verapamil, quinidine (used for cardiovascular conditions).

You should avoid taking PEXOLA 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 at the beginning of treatment with PEXOLA.

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 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

Take PEXOLA tablets every day exactly as your doctor told you. 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 is too strong or too weak, talk to your doctor or pharmacist.

Parkinson's Disease:
- PEXOLA tablets are usually taken three times a day. Your doctor will slowly (every 5 to 7 days) increase the dose of PEXOLA until the medicine controls your symptoms.

Usual adult ascending-dose schedule for PEXOLA in Parkinson's Disease:

Week 1:	PEXOLA 0,125 mg taken three times a day
Week 2:	PEXOLA 0,25 mg taken three times a day
Week 3:	PEXOLA 0,5 mg taken three times 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 have moderate renal (kidney) problems, your doctor may recommend lower doses than those listed above or may advise you to take PEXOLA tablets twice daily rather than three times a day.

Restless Legs Syndrome (RLS):
- The dose is usually taken once a day, in the evening, 2-3 hours before bedtime.
- During the first week, the usual dose is one tablet PEXOLA 0,125 mg **once** a day.
- This may be increased every 4 - 7 days as directed by your doctor until your symptoms are controlled (maintenance dose).
- The daily dose should not exceed 0,75 mg.

Usual adult ascending-dose schedule for PEXOLA in RLS:
Week 1: PEXOLA 0,125 mg taken once a day, in the evening.
Week 2:* PEXOLA 0,25 mg taken once a day, in the evening.
Week 3:* PEXOLA 0,5 mg taken once a day, in the evening.
Week 4:* PEXOLA 0,75 mg taken once a day, in the evening.
* 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.

If you take more PEXOLA than you should:
Overdosage could cause 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:
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.
Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with PEXOLA is stopped:
Do not stop taking PEXOLA without first talking to your doctor.
If you have to stop taking this medicine for Parkinson's disease 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.

If you suffer from Parkinson's disease you should not stop treatment with PEXOLA 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 can cause side-effects.

If you suffer from Parkinson's disease, you may experience the following side-effects:

Frequent:

- dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- dizziness including dizziness when standing up
- sleepiness
- hypotension (low blood pressure)
- nausea (feeling sick)
- urge to behave in an unusual way (inappropriate change in behaviour e.g. uncontrolled gambling, binge eating, spending money inappropriately, and increased sexual desire which may be inappropriate)
- abnormal dreams
- confusion
- hallucinations (seeing, hearing, experiencing or feeling things that are not there)
- sleeplessness (insomnia)
- restlessness
- amnesia (memory disturbance)
- headache
- visual disturbance
- shortness of breath (dyspnoea)
- constipation
- vomiting (being sick)
- tiredness (fatigue)
- fluid accumulation (swelling from fluid), usually in the legs (peripheral oedema)
- weight loss.

If you suffer from Restless Legs Syndrome, you may experience the following side-effects:

Frequent:

- nausea (feeling sick)
- abnormal dreams
- changes in sleep pattern, such as sleeplessness (insomnia) and sleepiness
- dizziness
- headache
- constipation
- vomiting (being sick)
- tiredness (fatigue).

There have been patients taking PEXOLA tablets who have 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, tell your doctor.

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

6. STORING AND DISPOSING OF PEXOLA

Store PEXOLA tablets in a dry and cool place (below 30 °C).
Keep PEXOLA tablets in the original blister pack until needed. Once the tablets have been taken out of the blister pack, protect the tablets from light.

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

Cartons containing 100 tablets packed in aluminium blister strips of 10 tablets per strip.

8. IDENTIFICATION OF PEXOLA

PEXOLA 0,125 mg: Flat, round, white tablets with bevelled edges and marked with P6 on the one side and the Company logo on the other side of the tablet.

PEXOLA 0,25 mg: Flat, oval, white tablets with bevelled edges and marked P7/deep breakline/P7 on the one side and Company logo/breakline/Company logo on the other side of the tablet.

PEXOLA 1,0 mg: Flat, round, white tablets with bevelled edges and marked with P9/deep breakline/P9 on the one side and Company logo/breakline/Company logo on the other side of the tablet.

9. REGISTRATION NUMBERS

PEXOLA 0,125 mg: 32/5.4.1/0298
PEXOLA 0,25 mg: 32/5.4.1/0299
PEXOLA 1,0 mg: 32/5.4.1/0300

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

Ingelheim Pharmaceuticals (Pty) Ltd
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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

19 April 2013