Applicant: Teva Pharmaceuticals (Pty) Ltd	**Product name and strength: PRAMIPEXOLE ER TEVA: Each extended release tablet contains 0,75 mg; 0,375 mg;1,5 mg; 3,0 mg or 4,5 mg pramipexole dihydrochloride monohydrate equivalent to 0,52 mg; 0,26 mg; 1,05 mg; 2,1 mg or 3,15 mg**

APPROVED PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S4

PRAMIPEXOLE ER 0,375 TEVA, extended release tablets

PRAMIPEXOLE ER 0,75 TEVA, extended release tablets

PRAMIPEXOLE ER 1,5 TEVA, extended release tablets

PRAMIPEXOLE ER 3,0 TEVA, extended release tablets

PRAMIPEXOLE ER 4,5 TEVA, extended release tablets

Pramipexole

Sugar free

Read all of this leaflet carefully before you start taking PRAMIPEXOLE ER TEVA:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- PRAMIPEXOLE ER TEVA 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.

WHAT IS IN THIS LEAFLET:

1. WHAT PRAMIPEXOLE ER TEVA IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PRAMIPEXOLE ER TEVA

3. HOW TO TAKE PRAMIPEXOLE ER TEVA

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE PRAMIPEXOLE ER TEVA

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT PRAMIPEXOLE ER TEVA IS AND WHAT IT IS USED FOR:

PRAMIPEXOLE ER TEVA 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.

PRAMIPEXOLE ER TEVA is used in the treatment of symptoms and signs of Parkinson's disease. It may be used as a single medicine or in combination with levodopa (another medicine for Parkinson's disease).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PRAMIPEXOLE ER TEVA:

Do not take PRAMIPEXOLE ER TEVA:

- if you are hypersensitive (allergic) to pramipexole or any of the other ingredients of PRAMIPEXOLE ER TEVA
- if you are younger than 18 years of age
- if you have moderate to severe kidney impairment.

Warnings and precautions:

Take special care with PRAMIPEXOLE ER TEVA:

Talk to your doctor before taking PRAMIPEXOLE ER TEVA. Tell your doctor if you have (had) or develop any medical conditions or symptoms, especially any of the following:

- sleepiness and episodes of suddenly falling asleep
- 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 PRAMIPEXOLE ER TEVA
- 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
- psychosis (e.g. comparable with symptoms of schizophrenia)
- vision impairment. You should have regular eye examinations during treatment with PRAMIPEXOLE ER TEVA
- melanoma (a type of skin) may be more common in patients with Parkinson's disease
- 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 upon standing up)
- 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, 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 ER TEVA treatment. If the problems persist more than a few weeks, your doctor may need to adjust your treatment
- PRAMIPEXOLE ER TEVA 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 ER TEVA is not recommended for use in children or adolescents under 18 years.

Other medicines and PRAMIPEXOLE ER TEVA:

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

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)

- cisplatin(to treat various types of cancers)
- procainamide (to treat irregular heartbeat)
- 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)
- ranitidine (to decrease stomach acid production)
- diltiazem and verapamil (to treat high blood pressure)
- triamterene (a diuretic)
- neuroleptic medicines which are used to treat psychiatric disorders (phenothiazines, butyrophenones, thioxanthenes) and metoclopramide (to treat nausea and vomiting) may decrease the effectiveness of PRAMIPEXOLE ER TEVA.

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

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

PRAMIPEXOLE ER TEVA with food, drink and alcohol:

You should be cautious while drinking alcohol during treatment with PRAMIPEXOLE ER TEVA.

PRAMIPEXOLE ER TEVA can be taken with or without food.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before taking PRAMIPEXOLE ER TEVA.

The safety of PRAMIPEXOLE ER TEVA in pregnancy and lactation has not been established and should not be taken.

The effect of PRAMIPEXOLE ER TEVA on the unborn child is not known.

PRAMIPEXOLE ER TEVA should not be used during breastfeeding. PRAMIPEXOLE ER TEVA can reduce the production of breast milk.

It can also pass into the breast milk and can reach your baby. If use of PRAMIPEXOLE ER TEVA is unavoidable, breastfeeding should be stopped.

Driving and using machines:

PRAMIPEXOLE ER TEVA can cause hallucinations (seeing, hearing or feeling things that are not there). If affected, do not drive or use machines.

PRAMIPEXOLE ER TEVA has 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.

3. HOW TO TAKE PRAMIPEXOLE ER TEVA:

Do not share medicines prescribed for you with any other person.

Always take PRAMIPEXOLE ER TEVA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

PRAMIPEXOLE ER TEVA should be taken once daily at about the same time each day.

PRAMIPEXOLE ER TEVA extended release tablets should be swallowed whole with water and may be taken with or without food.

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

Dosages should be increased gradually from a starting dose of 0,375 mg per day and then increased every 7 days. If you do not experience intolerable side effects, your doctor will increase your dose gradually to achieve a maximal therapeutic effect.

The usual maintenance dose ranges from 0,375 mg to a maximum of 4,5 mg per day.

If you are also using a medicine known as levodopa your doctor will lower the dose of levodopa.

If you have impaired kidney function your doctor will determine your dose according to your kidney function.

Dose reduction is not considered necessary if you have impaired liver function.

Your doctor will tell you how long your treatment with PRAMIPEXOLE ER TEVA will last. If you have the impression that the effect of PRAMIPEXOLE ER TEVA is too strong or too weak, tell your doctor or pharmacist.

If you take more PRAMIPEXOLE ER TEVA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

You may experience vomiting, restlessness, or any of the side effects as described in **section 4: Possible side effects.**

If you forget to take PRAMIPEXOLE ER TEVA:

Do not take a double dose to make up for forgotten individual doses.

If you forget to take a dose of PRAMIPEXOLE ER TEVA but remember within twelve hours, take your tablet straightaway 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.

If you stop taking PRAMIPEXOLE ER TEVA:

Do not stop taking PRAMIPEXOLE ER TEVA 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.

If you suffer from Parkinson's disease you should not stop treatment with PRAMIPEXOLE ER TEVA 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.

4. POSSIBLE SIDE EFFECTS:

PRAMIPEXOLE ER TEVA can have side effects.

Not all side-effects reported for PRAMIPEXOLE ER TEVA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PRAMIPEXOLE ER TEVA, please consult your healthcare provider for advice.

If any of the following happens, stop taking PRAMIPEXOLE ER TEVA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to PRAMIPEXOLE ER TEVA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects that can occur frequently:

- dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- sleepiness
- dizziness
- nausea
- urge to behave in an unusual way
- hallucinations (seeing, hearing or feeling things that are not there)
- confusion
- tiredness (fatigue)
- sleeplessness (insomnia)
- excess of fluid, usually in the legs (peripheral oedema)
- headache
- hypotension (low blood pressure)
- abnormal dreams
- constipation
- visual impairment
- vomiting (being sick)

- weight loss including decreased appetite.

Tell your doctor if you notice any of the following side effects that can occur less frequently:

- paranoia (e.g. excessive fear for one's own well-being)
- delusion
- excessive daytime sleepiness and suddenly falling asleep
- amnesia (memory disturbance)
- hyperkinesia (increased movements and inability to keep still)
- weight increase
- allergic reactions (e.g. rash, itching, hypersensitivity)
- fainting
- cardiac failure (heart problems which can cause shortness of breath or ankle swelling)*
- inappropriate antidiuretic hormone secretion
- dyspnoea (difficulty breathing)
- hiccups
- pneumonia (infection of the lungs)
- 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)

- delirium (decreased awareness, confusion, loss of reality)
- mania (agitation, feeling elated or over-excited).

Side effects with unknown frequency:

- after stopping or reducing your PRAMIPEXOLE ER TEVA treatment: Depression, apathy, anxiety, fatigue, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS)
- abnormal behaviour, abnormal dreams, compulsive shopping, hallucinations (all kinds), increased eating (including binge eating, compulsive eating, and hyperphagia), libido disorders (including increased and decreased libido, and hypersexuality), pathological gambling
- accidents (including fall), blackouts, fatigue, headache, fainting
- heart failure
- low blood pressure
- vomiting
- spontaneous erections
- weight increase.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reaction Reporting Form, found online under

SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PRAMIPEXOLE ER TEVA.

5. HOW TO STORE PRAMIPEXOLE ER TEVA:

Store all medicine out of reach of children.

Store at or below 25 °C.

Keep blisters in the original carton until required for use.

Return the expired medicine to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What PRAMIPEXOLE ER TEVA contains:

The active substance is pramipexole.

Each extended release tablet contains 0,75 mg; 0,375 mg;1,5 mg; 3,0 mg or 4,5 mg pramipexole dihydrochloride monohydrate equivalent to 0,52 mg; 0,26 mg; 1,05 mg; 2,1 mg or 3,15 mg, respectively.

The other ingredients are colloidal silicon dioxide, dibasic calcium phosphate hypromellose 2208 fibrous powder, hypromellose 2208 granular powder, magnesium stearate.

What PRAMIPEXOLE ER TEVA looks like and contents of the pack:

PRAMIPEXOLE ER 0,375 TEVA: The round tablets of 9 mm diameter are white or nearly white, have a flat surface with bevelled edges and are marked with '026' on one side.

PRAMIPEXOLE ER 0,75 TEVA: The round tablets of 10 mm diameter are white or nearly white, biconvex and are marked with '052' on one side.

PRAMIPEXOLE ER 1,5 TEVA: The round tablets of 10 mm diameter are white or nearly white, biconvex and are marked with '105' on one side.

PRAMIPEXOLE ER 3,0 TEVA: The round tablets of 10 mm diameter are white or nearly white, biconvex and are marked with '210' on one side.

PRAMIPEXOLE ER 4,5 TEVA: The round tablets of 11 mm diameter are white or nearly white, have a flat surface with bevelled edges and are marked with '315' on one side.

PRAMIPEXOLE ER TEVA extended release tablets are packed in silver Al/OPA-Al-PVC blisters. 10 tablets per blister. Cartons contain 10, 30 or 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd.

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Midrand

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2090

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This leaflet was last revised in:

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Registration numbers:

PRAMIPEXOLE ER 0,375 TEVA: 50/5.4.1/0800

PRAMIPEXOLE ER 0,75 TEVA: 50/5.4.1/0801

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name and strength: PRAMIPEXOLE ER TEVA: Each extended release tablet contains 0,75 mg; 0,375 mg;1,5 mg; 3,0 mg or 4,5 mg pramipexole dihydrochloride monohydrate equivalent to 0,52 mg; 0,26 mg; 1,05 mg; 2,1 mg or 3,15 mg

PRAMIPEXOLE ER 1,5 TEVA: 50/5.4.1/0802

PRAMIPEXOLE ER 3 TEVA: 50/5.4.1/0803

PRAMIPEXOLE ER 4,5 TEVA: 50/5.4.1/0804