PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

Madopar® (Tablets)

Madopar® HBS (Capsules)

Read all of the leaflet carefully before you start taking/using Madopar

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

Each Madopar® tablet contains 200 mg levodopa and 50 mg benserazide.

The other ingredients are calcium hydrogen phosphate, colloidal anhydrous silica, crospovidone, docusate sodium, ethylcellulose, iron oxide red (E172), magnesium stearate, mannitol, microcrystalline cellulose, pregelatinised maize starch.

Each Madopar® HBS capsule contains 100 mg levodopa and 25 mg benserazide.

The other ingredients are calcium hydrogen phosphate, gelatin, hydrogenated vegetable oil, indigo carmine, iron oxide yellow, magnesium stearate, mannitol, methyl hydroxypropylcellulose, povidone, talc, titanium dioxide and TEKPRINT SW-1102 red ink used as a printing ink.

WHAT MADOPAR IS USED FOR

Madopar is used to treat Parkinson's disease.

People with Parkinson's disease do not have enough dopamine in certain parts of their brains. This can result in slow movements, stiff muscles and tremor.

Madopar belongs to a group of medicines called antiparkinsonian agents. Antiparkinsonian agents are used to treat Parkinson's disease and work on the central nervous system. The symptoms of Parkinson's disease are caused by a deficiency of a natural substance in the nervous system. Madopar helps to replace this substance. By improving muscle control, Madopar allows more normal movements of the body.

BEFORE YOU TAKE MADOPAR

Do not take Madopar if you are allergic (hypersensitive) to:

- Levodopa, benserazide or any of the other ingredients of Madopar (see WHAT MADOPAR CONTAINS).

Do not take MADOPAR if:

- You are taking or have taken medicines known as monoamine oxidase inhibitors (MAOI) (e.g. tranylcypromine, phenelzine) in the past 14 days.
- You have taken a combination of a selective MAO-A inhibitor (e.g. moclobemide) with a selective MAO-B inhibitor (e.g. selegiline)
- You suffer from a hormonal disorder, e.g. an overactive thyroid gland.
- You have untreated heart, liver, kidney, lung, blood or endocrine (hormonal) disease
- You have a problem with pressure in your eyes called 'glaucoma'.
- You suffer from certain nervous or psychiatric disorders which make you distressed and anxious, or may make you lose contact with reality and become unable to think and judge clearly.
- You are under 25 years of age. This is because your bones may not have finished developing and treatment may affect your bone growth.

- You are pregnant, trying to become pregnant or are breastfeeding.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Madopar.

Take special care with Madopar

Check with your doctor or pharmacist before taking Madopar if:

- You have diabetes (high blood sugar).
- You have a lung condition.
- You have heart problems, particularly an uneven heart beat (dysrrhythmia) or you have had a heart attack.
- You have hypertension (high blood pressure).
- You have an ulcer in your stomach.
- You have osteoporosis or osteomalacia which causes problems with the strength of your bones.
- You have convulsions (fits)
- You have any compulsive behaviour disorder
- You are feeling down (depression) or other psychological disorder

Your doctor will discuss the risks and benefits of taking Madopar when pregnant or while breastfeeding

Operations

If you are going to have an operation, tell the doctor that you are taking Madopar. This is because you may need to stop taking Madopar before you have a general anaesthetic.

Pregnancy and breastfeeding

Do not take Madopar if you are pregnant, trying to get pregnant or breastfeeding. This is because Madopar may affect your baby. It is important for women to use contraception while taking Madopar.

If you get pregnant while taking Madopar, talk to your doctor straight away.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking Madopar.

Driving and using machinery

Talk to your doctor about driving and using machines or tools, when you take Madopar. This is because one of the medicines in Madopar, levodopa, can make you feel very sleepy. This can happen very quickly, even during the day. You must not drive or use machines if this happens to you. If you are in any doubt about whether you can do a particular activity, talk to your doctor.

When taken with certain foods

Madopar may not work as well as usual when taken with a protein rich meal (e.g. meat).

If possible Madopar should be taken either 30 minutes before or one hour after a meal. However, Madopar may also be taken with food.

Tablets or capsules should be swallowed whole with a glass of water or non-alcoholic drink.

Taking other medicines with Madopar

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines)

Do not take Madopar if you have taken a medicine for depression called a 'monoamine oxidase inhibitor' (MAOI) in the last 14 days. If this applies to you, do not take Madopar and ask your doctor or pharmacist for advice.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines for Parkinson's disease, such as amantadine, 'anticholinergics' and 'dopamine agonists'.
- Treatment for high blood pressure (hypertension), in particular reserpine.
- 'Sympathomimetics' – such as epinephrine (adrenaline), norepinephrine (noradrenaline) and isoproterenol (used to treat problems with your heart or asthma); cough and cold medicines containing pseudoephedrine.
- Blood pressure-lowering medications (e.g. metoprolol, atenolol)

- Anaesthetics, particularly halothane. If you know you are going to have an operation speak to your doctor about stopping Madopar 2-3 days beforehand.
- Amphetamines – medicines used for attention deficit disorder, feeling sleepy during the day (narcolepsy) or to help control appetite and weight gain.
- Ferrous sulphate (used to treat low levels of iron in the blood).
- Metoclopramide (used to treat problems with digestion).
- Antacids (used for stomach acid if you have indigestion).

Tests

If you need to have tests on your blood or urine, tell the doctor or nurse that you are taking Madopar. This is because Madopar may affect the results of some tests.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Madopar.

HOW TO TAKE MADOPAR

Always take Madopar exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Madopar tablets

- The tablets can be broken into smaller pieces to make it easier to swallow. Madopar tablets can be broken across the score line.
- Take them with or without food.
- Treatment is usually started with a low dose.
- The usual starting dose is ½ tablet three times a day.
- Your doctor will then slowly increase your dose every 2 to 3 days to find a dose which will adequately control your symptoms.

Madopar HBS (slow release) capsules

The Madopar HBS capsule is different to Madopar tablets. It takes longer to start working but its effects last longer.

- Swallow the capsules whole with a little water (do not crush or chew them).
- Take them with or without food.
- The capsules must not be opened before ingestion because the controlled release characteristics will be lost.
- Treatment is usually started with a low dose.
- This dose is slowly increased to find a dose which will adequately control your symptoms.

During this initial period your condition may become worse until the right dose is found for you. Your doctor may want to supervise you closely during this time.

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

If you take more Madopar than you should

- If you take more Madopar than you should, or if someone else takes your Madopar tablets by mistake, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.
- The following effects may happen if you have taken more tablets that you should: nausea, vomiting, dizziness, feeling sleepy, changes in your heart beat, confusion and unusual movements of different parts of the body that you cannot control.

If you forget to take Madopar

- If you forget to take a dose, skip the missed dose. Then take your next dose when it is due.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

Stopping Madopar

- Do not stop taking Madopar without talking to your doctor.
- This is because if you stop taking Madopar suddenly it can cause something called ‘neuroleptic malignant-like syndrome’ (NMLS). Early signs include increased shaking, sudden high body

temperature and muscle problems including stiffness and trouble with balance and keeping upright, especially if seen with sweating, paleness and fast heart beat. NMLS can be life threatening.

If someone else takes your Madopar by mistake, they should talk to a doctor or go to a hospital straight away.

When you start Madopar you will need to take it for a long time. Continue taking Madopar until your doctor tells you to stop.

Do not share Madopar prescribed for you with another person.

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

POSSIBLE SIDE EFFECTS

Madopar can have side effects.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Madopar. You may need medical treatment if you get some of the side effects.

Not all side effects reported for Madopar are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Madopar, consult your doctor, pharmacist or other healthcare professional for advice.

See your doctor as soon as possible if you get the following side effects:

- Allergic reactions. The signs include a rash and feeling itchy.
- Heart beat that is uneven or is faster or slower than normal.
- Bleeding in your stomach or intestines. You may see blood in your stools (they may look black and tarry) or blood when you are sick (this may look like coffee grounds).
- Low numbers of all types of white blood cells. The signs include infections of your mouth, gums, throat and lungs.

- Reduced numbers of red blood cells, white blood cells and platelets in your blood. This may make you feel tired, get infections more easily, or bruise more easily or have nose bleeds.

Other possible side effects:

Not known (frequency cannot be estimated from the available data)

Stomach and gut:

- Loss of appetite, feeling sick or being sick or diarrhoea, particularly at the start of your treatment. To help with this, your doctor may tell you to take Madopar with some food or drink or increase your dose more slowly.
- A change in the colour of your saliva, tongue, teeth or inside of your mouth.

Heart and circulation:

- Feeling dizzy when you stand up. This usually gets better if your dose is lowered.

Blood:

- Low numbers of red blood cells (anaemia). The signs include feeling tired, pale skin, palpitations (a fluttering sensation in your heart) and being short of breath.
- Changes to your liver or blood - shown in a blood test.

Mental problems:

- Feeling excited, anxious, agitated, depressed, aggressive or disorientated (the feeling of being lost).
- Believing things which are not true, hallucinations (seeing and possibly hearing things that are not really there) or losing contact with reality.
- Feeling sleepy, sometimes during the daytime.
- Falling asleep suddenly.
- Having difficulty sleeping.

Impulse Control Disorders:

You may experience an inability to resist the impulse to perform an action that could be harmful, 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).

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

Others:

- Unusual movements of different parts of your body which you cannot control. This may affect your hands, feet, face or tongue. Your doctor may change your dose of Madopar to help with these effects.
- You may experience 'on-off' effects. This is where you can switch quite suddenly between being 'on' and able to move, and being 'off' and immobile.
- An irresistible urge to move the legs and sometimes the arms.
- Changes to how things taste or a loss of taste.
- Redness of the face or neck.
- Sweating.
- Your urine (water) may become slightly red. This is not a cause for concern. It is caused by your body getting rid of the medicine.

STORING AND DISPOSING OF MADOPAR

- Store Madopar tablets and capsules in their bottle, with the lid closed to protect the tablets from light and moisture.
- Madopar tablets and capsules should be kept at a temperature below 25 °C.
- Keep out of the reach and sight of children.
- Do not use Madopar after the expiry date (EXP) stated on the pack.
- Do not throw away any left over tablets or capsules. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to.

PRESENTATION OF MADOPAR

Madopar Tablets: Amber glass bottles containing 100 tablets.

Madopar HBS Capsules: Amber glass bottles containing 30 or 100 capsules.

IDENTIFICATION OF MADOPAR

Madopar Tablets: Pale red, slightly speckled, cylindrical biconvex tablets.

Imprint: Upper face: ROCHE with hexagon, cross-break mark. Lower-face: cross-break mark.

Madopar HBS Capsules: Opaque dark green (cap) and light blue (body) capsules with an imprint Roche, containing white to trace-yellowish, fine granular powder.

REGISTRATION NUMBER

Madopar Tablets: P/5.4.1/150

Madopar HBS Capsules: 31/5.4.1/0194

NAME AND ADDRESS OF REGISTRATION HOLDER

Roche Products (Pty) Ltd

90 Bekker Road

Hertford Office Park, Building E

Vorna Valley, Midrand

South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

DATE OF PUBLICATION

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