



## **PATIENT INFORMATION LEAFLET**

### **SCHEDULING STATUS**

**S4**

**Madopar® tablets 200/50 mg**

**levodopa and decarboxylase inhibitor benserazide**

**Contains sugar (mannitol 103,20 mg per tablet)**

**Read all of this leaflet carefully before you start taking 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 is in this leaflet**

1. What Madopar is and what it is used for
2. What you need to know before you take Madopar
3. How to take Madopar
4. Possible side effects
5. How to store Madopar
6. Contents of the pack and other information

#### **1. What Madopar is and what it is used for**

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

*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 works 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.

## **2. What you need to know before you take Madopar**

### **Do not take Madopar if:**

- You are allergic (hypersensitive) to levodopa, benserazide or any of the other ingredients of Madopar
- You are allergic to any ingredients listed in section 6.
- You are taking or have taken medicines known as monoamine oxidase inhibitors (MAOI) (e.g. tranylcypromine, phenelzine, moclobamide, selegiline) in the past 14 days.
- 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 your baby.

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

### **Warnings and precautions**

Take special care with Madopar if:

- You have diabetes (high blood sugar).
- You have a lung condition.
- You have heart problems, particularly an uneven heart beat (dysrhythmia). 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 impulse control disorder.
- You are feeling down (depression) or other psychological disorders.

### **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.

### **Other medicines and 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 (see 'Do not take Madopar' above).

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.

### **Madopar and food**

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 to avoid food affecting the absorption of the capsule contents. However, if you get stomach problems when taking Madopar, you may take it with a low protein snack or liquid.

The tablets should be swallowed whole with a glass of water or a non-alcoholic drink.

### **Pregnancy and breastfeeding**

You must not take Madopar if you are pregnant or breastfeeding your baby (see 'Do not take Madopar').

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 Madopar.

This is because Madopar may affect your baby. It is important for women to use contraception while taking Madopar.

You must not take Madopar if you plan to become pregnant. Your doctor may do a pregnancy test to confirm that you are not pregnant before he will prescribe Madopar for you.



## **Driving and using machines**

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.

## **3. 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 without food especially those high in protein, 30 minutes to one hour before or after a meal (see 'Madopar and food' above).
- 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. The effective dosage is generally between 2 and 4 tablets daily, divided into three or four doses.

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**

In the event of overdose consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take the medicine pack with you.



The following effects may happen if you have taken more tablets than 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 a condition 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 overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

## **4. 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, please consult your health care provider for advice.

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

- abnormal involuntary jerking movements of the body. These are usually caused if your dose is too high and will lessen or disappear when your dose is reduced.
- mental changes including paranoia, depression, mania, agitation and hallucinations (seeing, feeling or hearing things that are not there).
- fluctuations in the effect of Madopar known as freezing (on-off) episodes. These can usually be helped by asking your doctor to adjust your dose.
- 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:**

**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:**

- 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.

### **Reporting of side effects**

If you get side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 Madopar.

### **5. How to store Madopar**

- Store Madopar tablets in their bottle, with the lid closed to protect the tablets from light and moisture.
- Madopar tablets should be kept at a temperature at or below 25 °C.
- Store out of the reach 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.

### **6. Contents of the pack and other information**

#### **What Madopar contains:**

Each Madopar tablet contains 200 mg levodopa and 50 mg decarboxylase inhibitor 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.

#### **What Madopar looks like and contents of the pack**

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



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

They are in an amber glass bottle containing 100 tablets.

### **Holder of Certificate of Registration**

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Roche Ethical Assistance Line toll-free: 0800 21 21 25

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