

PACKAGE LEAFLET: INFORMATION FOR THE USER

MADOPAR® 100 mg/25 mg DISPERSIBLE TABLETS
(levodopa/benserazide hydrochloride)

Your medicine is called Madopar® 100 mg/25 mg Dispersible Tablets but will be referred to as Madopar throughout the remainder of the leaflet.

Information for other strengths of Madopar (Madopar® 50 mg/12.5 mg Dispersible Tablets) also may be present in this leaflet.

Please read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

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
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1. What Madopar is and what it is used for

Madopar dispersible tablets contain two medicines called levodopa and benserazide. They are 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 like this:

- In your body the **levodopa** is changed into dopamine. Dopamine is the active medicine that is needed in your brain to help Parkinson's disease.
- The **benserazide** allows more of the levodopa you take to get into your brain, before it is changed into dopamine.

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 (listed in Section 6: Contents of the pack and other information).
- You have a problem with the pressure in your eyes called 'narrow-angle glaucoma'.
- You have serious problems with your kidneys, liver or heart.
- You have a serious problem with your hormones, such as an overactive thyroid gland.
- You have a severe mental problem which may make you distressed and anxious, or may make you lose contact with reality and become unable to think and judge clearly.
- You have depression and have taken a medicine called a 'non-selective monoamine oxidase inhibitor' (MAOI) in the last 14 days. These medicines include isocarboxazid and phenelzine. See the section on 'Other medicines and Madopar'.
- You are pregnant or trying to become pregnant. See the section on 'Pregnancy and breast-feeding'.
- You are under 25 years of age. This is because your bones may not have finished developing.
- You have ever had skin cancer.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Madopar if:

- You have a problem with the pressure in your eyes called 'wide-angle glaucoma'.
- You have problems with your hormones, kidneys, lungs or liver.
- You have diabetes (high blood sugar).
- You have heart problems, particularly an uneven heart beat (arrhythmia) or you have had a heart attack.
- You have any mental illness, such as depression.
- You have a 'peptic ulcer', an ulcer in your stomach, or in the tube leading from it ('duodenal ulcer').

You have something called 'osteomalacia' which causes problems with the strength of your bones.

Tell your doctor if you or your family/carer notices you are developing urges or cravings to behave in ways that are unusual for you or you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These behaviours are called impulse control disorders and can include addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

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

Other medicines and Madopar

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Madopar can affect the way some medicines work. Also some other medicines can affect the way Madopar works.

Do not take Madopar if you have taken a medicine for depression called a 'non-selective monoamine oxidase inhibitor' (MAOI) in the last 14 days. These medicines include isocarboxazid and phenelzine. 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 the following medicines:

- Other medicines for Parkinson's disease, such as amantadine, selegiline, bromocriptine, 'anticholinergics' called orphenadrine and benzhexol, 'dopamine agonists' called pergolide and ropinirole and a 'COMT inhibitor' called entacapone.
- Ferrous sulfate (used to treat low levels of iron in the blood).
- Antacids (used for stomach acid if you have indigestion).
- Metoclopramide (used to treat problems with digestion).
- Phenothiazines - such as chlorpromazine, promazine and prochlorperazine (used to treat mental illness).
- Thioxanthenes - such as flupentixol and zuclopenthixol (used to treat mental illness).
- Butyrophenones - such as haloperidol and benperidol (used to treat mental illness).
- Diazepam (used to treat anxiety and insomnia).
- Tetrabenazine (used to help problems controlling your muscle movement).
- Papaverine (used to improve blood flow around the body).
- Treatment for high blood pressure (hypertension), in particular reserpine.
- 'Sympathomimetics' – such as epinephrine, norepinephrine and isoproterenol (used to treat problems with your heart or asthma).
- Amphetamines - medicines used for attention deficit disorder, feeling sleepy during the day (narcolepsy) or to help control appetite and weight gain.
- Strong painkillers – such as codeine or morphine.
- Domperidone – used to help prevent you from feeling or being sick.

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 it before you have a general anaesthetic.

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 the medicine may affect the results of some tests.

Pregnancy and breast-feeding

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

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

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 told you. You should check with your doctor if you are not sure. How much you take and when you take it is different for different people.

How to take your tablets:

- Dissolve your tablets in a quarter of a glass of water or orange squash (not fresh orange juice). When you put the tablets in water, they break up quickly and the water will turn white. Stir well and drink within half an hour.
- Take them 30 minutes before or one hour after meals.

Patients NOT already treated with levodopa:

- The usual starting dose is one 50 mg/12.5 mg tablet (50 mg levodopa), three or four times a day.
- Your doctor will then increase your dose every 2 to 3 days until they find the right dose for you.

Patients already treated with levodopa:

- Your starting dose of Madopar will be one less 100 mg/25 mg tablet than the number of levodopa 500 mg tablets you take each day. For example, if you take four levodopa tablets (2000 mg levodopa) each day, your doctor will start by giving you three Madopar 100 mg/25 mg tablets daily.
- After one week your doctor may then start to increase your dose every 2 to 3 days until they find the right dose for you.

Patients already treated with a combined levodopa/decarboxylase inhibitor:

- The usual starting dose is one 50 mg/12.5 mg tablet (50 mg levodopa), three or four times a day.
- Your doctor will then increase your dose every 2 to 3 days until they find the right dose for you.

If you forget to take Madopar

- If you forget to take a dose, skip the missed dose. Then take the 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.

If you stop taking Madopar

You **must not** stop taking your tablets without talking to your doctor first. This is because if you stop taking the tablets 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 (postural instability) especially if seen with sweating, paleness and fast heart beat. NMLS can be life threatening.

If the above apply to you, talk to a doctor or go to a hospital straight away.

If you take more Madopar than you should

If you take more Madopar than you should, 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 than you should: changes in your heart beat, confusion, difficulty sleeping, feeling or being sick and unusual movements of different parts of the body that you cannot control.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Madopar can cause side effects, although not everyone will get them.

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 a low protein snack 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Madopar

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Do not store above 25°C. Store in the original package. Keep the bottle tightly closed in order to protect from moisture.
- Do not use after the expiry date printed on the carton or bottle label.
- If your doctor tells you to stop using the medicine, please take it back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Madopar contains

- Each dispersible tablet contains levodopa 100mg, benserazide 25mg (as the hydrochloride).
- Madopar also contain the following inactive ingredients: citric acid anhydrous, maize starch pregelatinised, microcrystalline cellulose and magnesium stearate.

What Madopar looks like and contents of the pack

- Madopar are white round tablets engraved 'ROCHE 125' on one side and a break line on the other side.
- Madopar is available in glass bottles in packs of 30, 60 (2 x 30), 90 (3 x 30) or 120 (4 x 30) tablets.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd., Chemilines House, Alperton Lane, Wembley, HA0 1DX.

Manufacturer

Madopar are manufactured by

- Roche S.p.A. - Via Morelli 2 - 20090 Segrate (MI), Italy. or
- Roche S.p.A., Viale G.B. Stucchi, 110 20900 Monza (MB), Italy.

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