

Package leaflet: Information for the patient

Roche

Madopar 200 mg/50 mg Hard Capsules

Levodopa and benserazide (as hydrochloride)

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
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

Madopar capsules 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: Further 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 'Taking other medicines'.
- 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 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 prochloroperazine (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).
- 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.
- 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.

It is recommended all women of childbearing potential take a pregnancy test before starting treatment.

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

Your doctor will tell you how many capsules to take. 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.

- Swallow the capsules whole with a little water (do not crush or chew them).
- Where possible, take Madopar in-between meals. This is because protein in a meal can reduce the speed and amount of the medicine's uptake within the body.
- Your doctor may advise you to take Madopar with a low protein snack or drink or increase your dose more slowly, particularly if you experience side effects of the stomach or gut at the start of your treatment.

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 capsules without talking to your doctor first. This is because if you stop taking the capsules suddenly it can cause something called 'neuroleptic malignant-like syndrome'. This can be life threatening.

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 capsules 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 capsules 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.

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.
- 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).
- A change in the colour of your saliva, tongue, teeth or inside of your mouth.

Skin:

- Allergic reactions. The signs include a rash and feeling itchy.

Heart and circulation:

- Heart beat may be uneven or go faster or slower.
- 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.
- Low numbers of all types of white blood cells. The signs include infections of your mouth, gums, throat and lungs.
- Low numbers of platelets in your blood. The signs include bruising easily and nose bleeds.
- 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.
- 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.
- Your saliva, tongue, teeth and inside your mouth may also become discoloured.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Madopar

- Store Madopar capsules in their bottle, with the lid closed to protect the capsules from moisture.
- Do not store Madopar capsules above 25°C.
- Keep out of the sight and reach of children.
- Do not use Madopar after the expiry date printed on the pack.
- Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Madopar contains

There are two active substances in Madopar 200 mg/50mg Hard Capsules.

Each capsule contains 200 mg levodopa and 50 mg benserazide as the hydrochloride.

Other ingredients in the capsules are Microcrystalline cellulose (E460), povidone (E1201), talc (E553b), magnesium stearate (E572), gelatin, indigo carmine (E132), titanium dioxide (E171), iron oxide (E172), black iron oxide (E172).

What Madopar capsules look like and contents of the pack

Madopar 200 mg/50 mg Hard Capsules are brown in colour at one end and pale blue at the other, with Roche printed in black ink on both ends.

Madopar capsules are supplied in amber coloured glass bottles containing 100 capsules.

Marketing Authorisation Holder

Roche Products (Ireland) Limited
3004 Lake Drive
Citywest
Naas Road
Dublin 24
Ireland

Manufacturer

Roche Pharma AG
Emil-Barell-Str. 1
D-79639 Grenzach-Wyhlen
Germany

This leaflet was last revised in January 2021.