

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Madopar® CR 100mg/25mg Prolonged Release Hard Capsules**  
**Modopar® CR 100mg/25mg Prolonged Release Hard Capsules**  
(levodopa and benserazide (as hydrochloride))

This product is available in the above names but will be referred to as Madopar CR throughout 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 CR is and what it is used for
2. What you need to know before you take Madopar CR
3. How to take Madopar CR
4. Possible side effects
5. How to store Madopar CR
6. Contents of the pack and other information

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

Madopar CR 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 CR 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.

The capsules are designed to release the medicines into your body slowly. This is why they are called 'CR' which stands for 'controlled release'.

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

**Do not take Madopar CR if:**

- You are allergic (hypersensitive) to levodopa, benserazide, peanut or soya, or any of the other ingredients of Madopar CR (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 CR if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before you take Madopar CR.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Madopar CR 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 CR.

**Other medicines and Madopar CR**

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 CR can affect the way some medicines work. Also some other medicines can affect the way Madopar CR works.

Do not take Madopar CR 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 CR 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.
- Ferrrous 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 CR. 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 CR. This is because the medicine may affect the results of some tests.

**Pregnancy and breast-feeding**

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

**Madopar CR contains soya oil**

If you are allergic to peanut or soya, do not use this medicinal product. (Refer to Section 6: Contents of the pack and other information.)

**3. How to take Madopar CR**

Always take Madopar CR 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).

**Patients NOT already treated with levodopa:**

- The usual starting dose is 1 capsule (100 mg levodopa), three times a day with meals.
- The starting dose should not be more than 6 capsules (600 mg levodopa) a day.
- Your doctor will then increase your dose every 2 to 3 days until they find the right dose for you.
- Some people may also need to take another medicine for Parkinson's disease with their first morning dose of Madopar CR. This is because Madopar CR releases the medicines slowly into the body.

**Patients already treated with levodopa:**

- Your doctor will start by giving you one Madopar CR capsule to replace each 100 mg of levodopa you have been taking.
- Your doctor will then increase your dose every 2 to 3 days until they find the right dose for you. This may take up to 4 weeks.
- At the start of treatment 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 forget to take Madopar CR**

- 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 CR**

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' (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 CR than you should**

If you take more Madopar CR 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 CR 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.