Package leaflet: Information for the patient **UK**

Madopar CR 100 mg/25 mg Prolonged Release Hard Capsules **Roche**
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

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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.
- 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).
- 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.

4. Possible side effects

Like all medicines Madopar CR 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 CR 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 CR 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 in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Madopar CR

- Store Madopar CR capsules in their bottle, with the lid closed to protect the capsules from moisture.
- Do not store Madopar CR capsules above 25°C.
- Keep out of the sight and reach of children.
- Do not use Madopar CR 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 CR contains
There are two active substances in Madopar CR 100 mg/25 mg Prolonged Release Hard Capsules. Each capsule contains 100 mg levodopa and 25 mg benserazide as the hydrochloride.

Other ingredients in the capsules are hypromellose (E464), hydrogenated vegetable oil (from refined, hydrogenated soya-bean oil and castor wax), calcium hydrogen phosphate anhydrous (E341), mannitol (E421), talc (E533b), povidone (E1201), magnesium stearate (E572), gelatin, indigo carmine (E132), titanium dioxide (E171), yellow iron oxide (E172) and red iron oxide (E172).

What Madopar CR looks like and contents of the pack
The capsules are green and blue in colour and have Roche printed on each end.

Madopar CR is supplied in amber coloured glass bottles containing 100 capsules.

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