

Madopar®

Contains active ingredient Levodopa and Benserazide

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What Madopar is used for

The name of your medicine is Madopar. It contains two active ingredients called levodopa and benserazide.

The symptoms of patients suffering from Parkinson's disease can be reduced by taking this medicine. Madopar does not, however, cure the disease, since the cause of the dopamine deficiency within the brain is not removed.

Your doctor, however, may have prescribed Madopar for another purpose.

Ask your doctor if you have any questions why Madopar has been prescribed for you.

This medicine is available only with a doctor's prescription.

How Madopar works

Madopar belongs to a group of medicines called antiparkinsonian agents and is used for the treatment of Parkinson's disease.

Antiparkinsonian agents are used to treat Parkinson's disease and work on the central nervous system. The symptoms of Parkinson's disease are caused by a deficiency of a natural substance in the brain called Dopamine. Madopar helps to replace this substance. By improving muscle control, Madopar allows more normal movements of the body.

Before you use Madopar

- When you must not use it

Do not take Madopar if:

- you have had an allergic reaction to any of the ingredients listed in the

Ingredients section of this leaflet

- you have taken a non- selective monoamine oxidase inhibitor (MAOI) medicine
- you have taken a combination of a selective MAO-A inhibitor such as moclobemide with a selective MAO-B inhibitor such as selegiline
- you have untreated heart, liver, kidney, lung, blood or endocrine (hormonal) disease
- you have narrow (closed) angle glaucoma (high pressure in the eye)
- you are being treated for severe mental illness
- you are under 25 years of age. This is because your bones may not have finished developing.
- you are pregnant or trying to become pregnant.

Do not take Madopar after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Madopar if the package is torn or shows signs of tampering.

If you are not sure if you should be taking Madopar, talk to your doctor.

- Before you start to use it

You must tell your doctor if:

- you are allergic to any other medicines, foods, dyes or preservatives
- you have any other health problems including:
 - convulsions (fits)
 - diabetes
 - stomach ulcers
 - feeling down (depression) or other psychological disorder
 - osteoporosis or osteomalacia
 - irregular heart beat
 - wide-angle glaucoma (high pressure in the eye)
 - any compulsive behaviour disorder
 - onset of sudden sleep disorder
 - other illnesses

- you plan to have surgery
- you are pregnant or plan to become pregnant
- you are breast-feeding or plan to breast-feed. Your doctor will discuss the risks and benefits of taking Madopar when pregnant or while breast- feeding.

If you have not told your doctor about any of the above, tell them before you start taking Madopar.

- Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought without a prescription from a pharmacy, supermarket or healthfood shop.

Other medicines may interfere with Madopar. These medicines include:

- 'Sympathomimetics' – such as epinephrine, norepinephrine and isoproterenol (used to treat problems with your heart or asthma).
- Treatment for high blood pressure (hypertension), in particular reserpine.
- other antiparkinsonian medications such as anticholinergics, amantadine, selegiline, bromocriptine and dopamine agonist
- medicines used for the control of abnormal movement disorders
- Ferrous sulphate (used to treat low levels of iron in the blood).
- medicines for relief nausea such as metoclopramide
- some medications used to treat mental illness, particularly the phenothiazine and butyrophenone derivatives such as. chlorpromazine, fluphenazine, prochlorperazine, thioridazine, trifluoperazine, or haloperidol
- general anaesthetics (medicines that put you to sleep before an operation), particularly cyclopropane and halothane. If you know you are going to have an operation, you should stop Madopar 12-48 hours beforehand. You should

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discuss this with your doctor first.

- opioids such as morphine, pethidine, methadone and codeine (may be present in some cough and cold or pain relieving medicines)
- antacids (medicines for heartburn, indigestion) should not be taken at the same time as Madopar HBS, as they interfere with the controlled release characteristics of Madopar HBS. Antacids can be taken at other times of the day.

Your doctor or pharmacist has more information on the medicines to be careful with or to avoid while taking Madopar.

If you have not told your doctor about any of the above, tell them before you start taking Madopar.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to use Madopar

Use Madopar exactly as your doctor has prescribed.

This may differ from the information contained in this leaflet.

- How much to use

Your doctor will tell you how many Madopar tablets or capsules to take each day.

The dose depends on your individual symptoms and your response. The dose of Madopar has to be carefully adjusted for each person. If you take too little Madopar your Parkinson's symptoms may not be controlled. If you take too much Madopar, you may experience unwanted effects. It may be several weeks before the best dose for you is reached.

Remember this is just a guide. This guide can be used for Madopar capsules or tablets.

Treatment with Madopar is usually started with lower doses. This may be increased each week until you have reached your required dose. Your doctor will decide which dose is best for you.

Do not stop taking Madopar without discussing with your doctor.

Madopar HBS (slow release) Capsules

Madopar HBS is different to other Madopar products. It takes longer to start working but its effects last longer.

If you change from normal Madopar to Madopar HBS, you start on the same number of capsules or tablets, but this is gradually increased by your doctor. Some people who change to Madopar HBS capsules might feel a little worse at first. This should only be temporary, but speak to your doctor if anything worries you.

Madopar Tablets

Madopar tablets can be broken across the score line. Any tablets which do not break cleanly along the line should not be taken.

- How to take it

Capsules or tablets should be swallowed whole with a glass of water or non-alcoholic drink. Do not chew capsules or tablets.

Madopar HBS capsules

Madopar HBS capsules should be swallowed whole and not chewed, opened or dissolved in liquid.

Madopar Tablet

Madopar 250 tablets can be broken across the score line. Any tablets which do not break cleanly along the line should not be taken.

- When to use it

If possible Madopar should be taken either 30 minutes before a meal or one hour after a meal. However, some patients may prefer to take Madopar with food.

If you have stomach upsets which can occur in the early stages of treatment with Madopar, try taking Madopar with a small snack (e.g. biscuit) or liquid. Tell your doctor if anything worries you.

- How long to use it

When you start Madopar you will need to take it long term. You may need at least 6 months before deciding if MADOPAR is working for you.

Continue taking Madopar until your

doctor tells you to stop.

- If you forget to use it

If you forget to take Madopar If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

Do not take a double dose to make up for one you have missed.

If you have trouble remembering your dose, ask your pharmacist for some hints.

If you are not sure what to do, ask your doctor or pharmacist.

- If you use too much (overdose)

If you think that you or anyone else may have taken too much Madopar, you may need urgent medical attention. Contact your doctor or visit the nearest Accident & Emergency Department immediately (bring along the medication, carton and this leaflet if possible).

While you are using it

- Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Madopar.

Tell your doctor if you become pregnant while taking Madopar.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the capsules or tablets are not helping your condition.

Tell your doctor if you suffer from sleepiness or sudden onset of sleep during daily activities.

Be sure to keep all of your appointments with your doctor so that your progress can be checked. Your doctor may want to perform regular tests while you are taking Madopar.

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- Things you must not do

Do not stop taking Madopar or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Madopar to anyone else even if their symptoms seem similar to yours.

Do not use Madopar to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

- Things to be careful of

Be careful driving or operating machinery until you know how Madopar affects you.

Madopar is associated with excessive drowsiness and very rarely with excessive daytime drowsiness and sudden sleep onset episodes. Tell your doctor if you experience these effects and do not drive or operate machinery until this has been resolved.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Madopar.

Madopar helps most people with Parkinson's Disease but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- 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)
- palpitations or changes in the rhythm or rate of the heartbeat, dizziness on standing up
- fluctuations in effect of Madopar seen as freezing episodes. These can usually be helped by having your doctor adjust your dose.
- nausea and vomiting
- loss of appetite
- skin rash or itching
- confusion, tiredness, sleeplessness, or sudden onset of sleep episodes
- poor muscle tone, hiccups
- restlessness
- water retention, cramps

These side effects are common, especially if you have just started Madopar.

You may experience the following side effects. Tell your doctor if you notice any of the following and they worry you:

- changes in sex drive or hypersexuality
- signs of compulsive behaviour (performing a repetitive purposeless activity)
- loss of taste
- your urine may be darker with a red tinge
- Other body fluids or tissues may also be discoloured or stained including saliva, the tongue, teeth or oral mucosa
- bleeding or bruising more easily, frequent infections such as fever, sever chills, sore throat or mouth ulcers

Tell your doctor immediately if you notice any of the following:

- palpitations, chest pain, dizziness
- diarrhoea,
- confusion

These may be serious side effects and your doctor may need to change your Madopar dose.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list. Ask your doctor or pharmacist if you don't understand anything in this list. Do not be alarmed by this list of possible side effects. You may not experience any of them

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Madopar

- Storage

Keep your capsules or tablets in the bottle, with the cap tightly closed, until it is time to take them.

If you take the capsules or tablets out of the bottle, or the cap is loose, they may not keep well.

Keep Madopar capsules and tablets in a **cool dry place where the temperature stays below 30°C.**

- Disposal

If your doctor tells you to stop taking Madopar, or the tablets/capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

- What it looks like

Madopar Roche 125 capsule is flesh coloured at one end and powder blue at the other end, with 'ROCHE' printed on both ends.

Madopar Roche HBS (slow- release) capsule is powder- blue at one end and dark green at the other end, with 'ROCHE' printed in red ink on both ends.

Madopar Roche Tablet 250 mg is pale red in colour, cross-scored on both sides with 'RO', 'C', 'HE' and a hexagon on one side.

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All Madopar capsules and tablets come in bottles of 100.

- **Ingredients**

- **Active ingredients**

Madopar Roche 125 capsule contains levodopa 100 mg and benserazide 25 mg.

Madopar Roche HBS (slow-release) capsules contains levodopa 100 mg and benserazide 25 mg.

Madopar Roche tablet 250 mg contains levodopa 200 mg and benserazide 50 mg

- **Inactive ingredients**

Madopar Roche 125 Capsule contains:
microcrystalline cellulose, talc, povidone K 90, magnesium stearate, indigo carmine (132), titanium dioxide (171), iron oxide red (E172) and gelatin.

Madopar Roche HBS (slow-release) capsule contains:
mannitol, talc, povidone K30, magnesium stearate, calcium hydrogen phosphate anhydrous, hypromellose, hydrogenated vegetable oil, indigo carmine (132), iron oxide yellow (172), titanium dioxide (171) and gelatin.

Madopar Roche tablet 250 mg contains:
mannitol, microcrystalline cellulose, crospovidone, magnesium stearate, pregelatinised maize starch, ethylcellulose, anhydrous calcium hydrogen phosphate, colloidal anhydrous silica, docusate sodium and iron oxide red (172).

- **MAL number**

Madopar Roche HBS capsule (MAL19900240ACRZ)
Madopar Roche 125 capsule (MAL19871097ACRZ)
Madopar Roche Tablet 250 mg (MAL19871099ACRZ)

Manufacturer

Made for
F. Hoffmann-La Roche Ltd,
Basel, Switzerland
by Delpharm Milano S.r.l,
production site Segrate, Italy.

Product Registration Holder

Roche (M) Sdn. Bhd. Level 21,
The Pinnacle, Persiaran Lagoon,
Bandar
Sunway, 47500 Subang Jaya,
Selangor.

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