

Consumer Medicine Information

Madopar

levodopa + benserazide

62.5 mg, 125 mg or 250 mg capsules

62.5 mg dispersible tablet

125 mg HBS capsule (controlled release capsule)

What is in this leaflet

This leaflet answers some common questions about MADOPAR tablets and capsules.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MADOPAR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What MADOPAR is used for

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

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

It is known that people with this disease have insufficient amounts of a substance called dopamine in certain areas of their brain. The signs of the illness are slow movements, stiff muscles and tremor and these may vary greatly from patient to patient. Levodopa is converted in the brain to dopamine, increasing the amounts in the brain toward normal levels. Benserazide itself does not enter the brain but it is there to prevent the conversion of levodopa to dopamine outside the brain. This helps to reduce unwanted effects in other parts of the body.

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 about why MADOPAR has been prescribed for you.

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

Before you take MADOPAR

When you must not take it

Do not take MADOPAR if:

1. you have had an allergic reaction to any of the ingredients listed in the Ingredients section of this leaflet
2. you have taken the non-selective monoamine oxidase inhibitors (MAOI) tranylcypromine (Parnate[®]) or phenelzine (Nardil[®]) within the last 2 weeks
3. you have taken a combination of a selective MAO-A inhibitor such as moclobemide (Apo-moclobemide[®]) with a selective MAO-B inhibitor such as selegiline (Eldepryl[®], Apo-Selegiline[®])
4. you have a heart, liver, or kidney condition or you suffer from a hormonal disorder
5. you have narrow (closed) angle glaucoma (high pressure in the eye)
6. you have a severe mental illness
7. you are under the age of 30 years old
8. you are pregnant or could become pregnant
9. the package is torn or shows signs of tampering
10. the expiry date printed on the pack has passed

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

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

Before you start to take it

Tell your doctor if:

1. you are pregnant or plan to become pregnant
you must not take MADOPAR if you are pregnant or plan to become pregnant.
2. you are breastfeeding or plan to breastfeed.
you should not take MADOPAR if you are breastfeeding or plan to breastfeed.
3. you have any other health problems, especially the following:
 - diabetes
 - glaucoma (high pressure in the eye)
 - depression or other psychological disorder
 - sudden onset of sleep disorder
4. you plan to have surgery
5. you are allergic to any other medicines, foods, dyes or preservatives

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

Taking certain foods

MADOPAR may not work as well as usual when taken with a protein-rich meal.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with MADOPAR. These medicines include:

- medicines used for the control of movement disorders
- those containing iron (Fergon[®], Ferrogradumet[®], Ferrograd C[®], Ferrograd-Folic[®])
- metoclopramide (Maxolon[®], Metamide[®], Paramax[®])
- sympathomimetics e.g. medicines containing ephedrine or pseudoephedrine (such as cough and cold medicines), adrenaline, isoprenaline, amphetamine
- blood pressure lowering medicines
- some medications used to treat mental illness known as irreversible non selective MAO inhibitors (Nardil[®], Apo-Moclobemide[®])
- general anaesthetics (medicines that put you to sleep before an operation). If you know you are going to have an operation, talk to your doctor beforehand.
- other antiparkinsonian agents e.g. anticholinergics (Atropine[®], Buscopan[®]), amantadine (Symmetrel[®])
- 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 medicines to be careful with or avoid while taking MADOPAR.

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

How to take MADOPAR

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

Take MADOPAR exactly as your doctor has prescribed.

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 as your Parkinson's symptoms will not be controlled if you take too little MADOPAR. 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 low doses e.g. one MADOPAR 62.5 three to four times a day. This may be increased over the next 4 to 6 weeks until you have reached your optimal dose. Usually, this dose will be MADOPAR 125 three to six times a day. Your doctor may prescribe other MADOPAR tablets or capsules to be taken as well as or instead of MADOPAR 125.

MADOPAR HBS is different from 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.

When you take MADOPAR HBS, your doctor may tell you to take a MADOPAR capsule or dispersible tablet in the morning as well to help maintain better control of your symptoms.

How to take it

Capsules should be swallowed whole with a glass of water or non-alcoholic drink.

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

Do not chew the capsules or tablets.

MADOPAR 62.5 dispersible tablets are for people who have difficulty swallowing whole tablets or who require the medicine to work quickly. They may be dispersed in at least 25 mL to 50 mL of water. The tablets will disintegrate completely within a few minutes giving a milky-looking liquid which you should drink within 30 minutes. Remember to stir the liquid immediately before taking.

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

When to take it

If possible, MADOPAR should be taken at least 30 minutes before a meal or one hour after a meal.

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 take MADOPAR

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 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 double a dose to make up for one you have missed.

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

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

In case of an overdose

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency Centre if you think that you or anyone else may have taken too much MADOPAR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take an overdose of MADOPAR, you will experience some or all of the symptoms described under side effects, but these symptoms will be more severe.

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

While you are taking MADOPAR

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 tablets or capsules 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.

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 they have the same condition as you.

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 or consulting a pharmacist.

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:

- nausea and vomiting, loss of appetite, diarrhoea, loss of taste
- skin rash or itching
- palpitations or changes in the rhythm or rate of the heart beat, dizziness on standing up
- bleeding or bruising more easily, frequent infections such as fever, severe chills, sore throat or mouth ulcers
- 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
- fluctuations in effect of MADOPAR seen as freezing episodes. These can usually be helped by having your doctor adjust your dose.
- agitation, anxiety, seeing, feeling or hearing things that are not there (hallucinations, delusions)
- depression (feeling sad)
- confusion, tiredness, drowsiness (sleepiness), episodes of suddenly falling asleep, inability to sleep
- your urine may be darker with a red tinge

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.

After taking MADOPAR

Storage

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

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

Keep MADOPAR capsules and HBS capsules in a cool dry place where the temperature stays below 30 °C.

Keep MADOPAR dispersible tablets in a cool dry place where the temperature stays below 25 °C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep MADOPAR where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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 MADOPAR looks like

There are 5 MADOPAR products to meet individual needs:

MADOPAR 62.5 dispersible tablets are white with a break bar.

MADOPAR 62.5 capsules are light grey at one end and powder blue at the other, with 'ROCHE' printed on both ends.

MADOPAR 125 capsules are flesh coloured at one end and powder blue at the other, with 'ROCHE' printed on both ends.

MADOPAR 250 capsules are caramel coloured at one end and powder blue at the other, with 'ROCHE' printed on both ends.

MADOPAR HBS capsules are light blue at one end and dark green at the other, with 'ROCHE' printed on both ends.

Ingredients

Active ingredients:

MADOPAR 62.5 capsules and dispersible tablets contain levodopa 50 mg and benserazide 12.5 mg.

MADOPAR 125 capsules and MADOPAR HBS capsules contain levodopa 100 mg and benserazide 25 mg.

MADOPAR 250 capsules contain levodopa 200 mg and benserazide 50 mg.

Inactive ingredients:

MADOPAR dispersible tablets contain: citric acid, maize starch, microcrystalline cellulose, magnesium stearate.

MADOPAR 62.5, 125 and 250 capsules all contain: microcrystalline cellulose, talc, povidone, magnesium stearate, indigo carmine, titanium dioxide, iron oxide (red, yellow or black), gelatin. MADOPAR 62.5 also contains mannitol.

MADOPAR HBS capsules contain: mannitol, talc, povidone, magnesium stearate, calcium hydrogen phosphate, hypromellose, hydrogenated vegetable oil, indigo carmine, iron oxide yellow, titanium dioxide, gelatin.

Manufacturer

MADOPAR is distributed by:

Roche Products (New Zealand) Limited
PO Box 12492 Penrose



Auckland 1642
NEW ZEALAND

Customer enquiries: 0800 656 464

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