

Consumer Medicine Information

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 the active ingredients called *levodopa and benserazide*.

MADOPAR belongs to a group of medicines called antiparkinsonian agents.

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 nervous system. MADOPAR helps to replace this substance. By improving muscle control, MADOPAR allows more normal movements of the body.

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.

Before you take MADOPAR

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 an irreversible monoamine oxidase inhibitor (MAOI) medicine (e.g. tranylcypromine, phenelzine) within the last 2 weeks
- you have taken a combination of a selective MAO-A inhibitor (e.g. moclobemide) with a selective MAO-B inhibitor (e.g. selegiline)
- you have untreated heart, liver, kidney, lung, blood or endocrine (hormonal) disease
- you have narrow angle glaucoma (high pressure in the eye)
- you are being treated for severe mental problems
- you have melanoma or suspected melanoma
- you are under the age of 30
- you are being treated for Huntington's chorea or intention tremor

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

If you take it 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.

You must tell your doctor if:

- 1. you are allergic to any other medicines, foods, dyes or preservatives**
- 2. 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
 - other illnesses
- 3. you are pregnant or intend to become pregnant**
- 4. you are breast-feeding or wish to breast-feed.**

Your doctor will discuss the risks and benefits of taking MADOPAR when pregnant or while breast-feeding.

When taken with certain foods

(levodopa and benserazide)

MADOPAR may not work as well as usual when taken with a protein rich meal (e.g. meat).

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 (e.g. cough and cold medicines containing pseudoephedrine), asthma preparations
- blood pressure lowering medications (e.g. metoprolol, atenolol)
- other antiparkinsonian medications
- some medications used to treat mental disorders, particularly the phenothiazine and butyrophenone derivatives (e.g. chlorpromazine, fluphenazine, prochlorperazine, thioridazine, trifluoperazine, haloperidol)
- anaesthetics, particularly cyclopropane and halothane. If you know you are going to have an operation, you should stop MADOPAR 2-3 days beforehand.

Your doctor or pharmacist has a complete list of medicines to avoid while taking MADOPAR.

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

Use MADOPAR exactly as your doctor has prescribed.

How to take MADOPAR

How much to take

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 low doses eg. one MADOPAR 125 three times a day. This may be increased by one MADOPAR 125 each week until you have reached your best dose. Usually, this dose will be 4-8 MADOPAR 125 a day. Your doctor may prescribe other MADOPAR tablets or capsules to be taken as well as or instead of MADOPAR 125.

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.

In the mornings when you take MADOPAR HBS, your doctor may tell you to take a normal MADOPAR to help maintain better control of your symptoms.

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

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

MADOPAR Rapid (dispersible) Tablets:

MADOPAR Rapid 62.5 and MADOPAR Rapid 125 tablets may be dissolved in at least 25-50mL of water. The tablets will dissolve 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.

When to take it

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

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.

In case of an overdose

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much MADOPAR 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 may 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.

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

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.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not stop taking MADOPAR or lower 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.

Things to be careful of

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

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 a few 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 and hallucinations
- nausea and vomiting
- loss of appetite
- weight gain
- constipation
- tiredness, sleeplessness
- poor muscle tone, hiccups
- restlessness
- water retention, cramps

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

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)

(levodopa and benserazide)

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.

After taking MADOPAR

Storage

Keep MADOPAR capsules and 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 this medicine.

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.

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

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

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 eight MADOPAR products to meet individual needs:

- MADOPAR 62.5 capsules are half blue and half grey in colour with 'ROCHE' printed on both ends.
- MADOPAR 125 capsules are half blue and half pink in colour with 'ROCHE' printed on both ends.
- MADOPAR 250 capsules are half blue and half caramel in colour with 'ROCHE' printed on both ends.
- MADOPAR HBS 125 (slow-release) capsules are half dark-green and half light-blue in colour with 'ROCHE' printed in red ink on both ends.
- MADOPAR 125 tablets are pale red in colour, cross-scored on both sides.

- MADOPAR 250 tablets are pale red in colour, cross-scored on both sides with 'RO', 'C', 'HE' and a hexagon on one side.
- MADOPAR Rapid 62.5 (disperible) tablets are off-white in colour, scored on one side and printed with 'ROCHE 62.5' on the other.
- MADOPAR Rapid 125 (disperible) tablets are off-white in colour, scored on one side and printed with 'ROCHE 125' on the other.

All MADOPAR tablets and capsules come in bottles of 100.

Ingredients

Active ingredients:

MADOPAR Capsules:

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

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

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

MADOPAR HBS 125 (slow-release) capsules contain levodopa 100 mg and benserazide 25 mg.

MADOPAR Tablets

MADOPAR 125 tablets contain levodopa 100 mg and benserazide 25 mg.

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

(levodopa and benserazide)

**MADOPAR Rapid (dispersible)
Tablets:**

MADOPAR Rapid 62.5 tablets contain levodopa 50 mg and benserazide 12.5 mg.

MADOPAR Rapid 125 tablets contain levodopa 100 mg and benserazide 25 mg.

Inactive ingredients:

MADOPAR Capsules:

MADOPAR 62.5, 125 and 250 capsules all contain:

microcrystalline cellulose, talc, povidone, magnesium stearate, indigo carmine (132), titanium dioxide (171), iron oxide (red, yellow or black - 172) and gelatin.

MADOPAR 62.5 capsules also contain mannitol.

MADOPAR HBS (slow-release) capsules contain:

mannitol, talc, povidone, magnesium stearate, calcium hydrogen phosphate, hypromellose, hydrogenated vegetable oil, indigo carmine (132), iron oxide yellow (172), titanium dioxide (171) and gelatin and TEKPRINT SW-1102 Red Ink used as a printing ink.

MADOPAR Tablets:

MADOPAR 125 and 250 tablets contain:

mannitol, microcrystalline cellulose, crospovidone, magnesium stearate, pregelatinised maize starch, ethylcellulose, anhydrous calcium hydrogen phosphate, colloidal anhydrous silica, docusate sodium and iron oxide red (172).

**MADOPAR Rapid (dispersible)
Tablets:**

MADOPAR Rapid 62.5 and Rapid 125 tablets contain:

citric acid, starch- maize, microcrystalline cellulose and magnesium stearate.

Manufacturer

MADOPAR is distributed by:
Roche Products Pty Limited

ABN 70 000 132 865
4 - 10 Inman Road
Dee Why NSW 2099

Customer enquiries: 1 800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers

MADOPAR Capsules:

- MADOPAR 62.5 - AUST R 13744
- MADOPAR 125 - AUST R 13746
- MADOPAR 250 - AUST R 13742
- MADOPAR HBS - AUST R 13743

MADOPAR Tablets:

- MADOPAR 125 - AUST R 43517
- MADOPAR 250 - AUST R 13745

MADOPAR Rapid Tablets:

- MADOPAR Rapid 62.5 - AUST R 59577
- MADOPAR Rapid 125 - AUST R 59576

This leaflet was prepared on
4 August 2010.