

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Madopar?

Madopar contains the active ingredients levodopa and benserazide. Madopar is used for the treatment of Parkinson's disease. For more information, see Section [1. Why am I using Madopar?](#) in the full CMI.

2. What should I know before I use Madopar?

Do not use if you have ever had an allergic reaction to levodopa or benserazide or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Madopar?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Madopar and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Madopar?

- Your doctor will tell you how many Madopar tablets or capsules to take each day. More instructions can be found in Section [4. How do I use Madopar?](#) in the full CMI.

5. What should I know while using Madopar?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using Madopar. - Tell the surgeon or anaesthetist that you are taking this medicine if you are going to have surgery. - Tell your doctor if you become pregnant whilst taking Madopar. - Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. - Tell your doctor if you feel that Madopar is not helping your condition. - Tell your doctor if you suffer from sleepiness or sudden onset of sleep during daily activities.
Things you should not do	- Do not stop taking Madopar or change the dose without first checking with your doctor. - Do not take any other medicines without first talking to your doctor.
Driving or using machines	- Be careful before you drive or use any machines or tools 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.
Looking after your medicine	- Store Madopar in a cool dry place away from moisture, heat or sunlight. Keep away from children - Keep your capsules or tablets in the bottle, with the cap tightly closed, until it is time to take them.

For more information, see Section [5. What should I know while using Madopar?](#) in the full CMI.

6. Are there any side effects?

Common side effects include; abnormal involuntary jerking movements of the body, mental changes including paranoia, depression, mania, agitation and hallucinations, fluctuations in the effect of Madopar known as freezing episodes, nausea and vomiting, loss of appetite, weight gain, constipation, skin rash or itching, confusion, tiredness, sleeplessness, or sudden onset of sleep episodes, poor muscle tone, hiccups, restlessness, water retention, cramps.

Serious side effects include; palpitations or changes in the rhythm or rate of the heartbeat, chest pain, dizziness on standing up, diarrhoea and confusion. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Madopar®

Active ingredients: levodopa and benserazide

Consumer Medicine Information (CMI)

This leaflet provides important information about using Madopar. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Madopar.**

Where to find information in this leaflet:

1. [Why am I using Madopar?](#)
2. [What should I know before I use Madopar?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Madopar?](#)
5. [What should I know while using Madopar?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Madopar?

Madopar contains the active ingredients levodopa and benserazide. Madopar belongs to a group of medicines called antiparkinsonian agents. Antiparkinsonian agents 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.

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.

Madopar is used for the treatment of Parkinson's disease.

2. What should I know before I use Madopar?

Warnings

Do not use Madopar if:

- you are allergic to levodopa or benserazide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have taken a non-selective monoamine oxidase inhibitor (MAO-I) medicine such as tranylcypromine or phenelzine within the last 2 weeks.
- you have taken a combination of a selective MAO-A inhibitor such as moclobemide with a selective MAO-B inhibitor such as selegiline or rasagiline.
- 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 (active psychosis or serious psychoneurosis).
- you have melanoma or suspected melanoma
- you are under the age of 30.
- you are being treated for Huntington's chorea or intention tremor.

Check with your doctor if you:

- have any other medical conditions including; convulsions (fits), diabetes, stomach ulcers, feeling down (depression) or other psychological disorders, osteoporosis or osteomalacia, irregular heart beat, wide-angle glaucoma (high pressure in the eye), any compulsive behaviour disorder, onset of sudden sleep disorder or any other illnesses.
- plan to have surgery.
- take any medicines for any other condition.
- are allergic to any other medicines, foods, dyes or preservatives.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Madopar should not be taken during pregnancy. You should use effective contraception to avoid becoming pregnant while you are being treated with Madopar.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss the risks and benefits of taking Madopar when breastfeeding.

When taken with certain foods

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Madopar and affect how it works. These medicines include:

- sympathomimetics such as cough and cold medicines containing ephedrine or pseudoephedrine, adrenaline, noradrenaline, isoprenaline, dexamphetamine, asthma preparations, epi-pens.

- blood pressure lowering medications such as metoprolol, atenolol.
- other antiparkinsonian medications such as anticholinergics, amantadine, selegiline, bromocriptine and dopamine agonists.
- medicines containing iron.
- medicines for relief of nausea such as metoclopramide.
- some medications used to treat mental illness, particularly the phenothiazines, tricyclic antidepressants 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 2-3 days beforehand. You should 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Madopar.

4. How do I use 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 to the medicine. The dose of Madopar has to be carefully adjusted for each person. If you take too little Madopar your symptoms may not be controlled. If you take too much Madopar, you may experience unwanted effects. It may take 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.
- Follow the instructions provided and use Madopar until your doctor tells you to stop.

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.
- When you take Madopar HBS, your doctor may tell you to take a Madopar capsule or Madopar Rapid (dispersible) tablet in the morning to help maintain better control of your symptoms.

How to take Madopar

Madopar Capsules

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

• Madopar HBS Capsules

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

• Madopar Rapid (dispersible) Tablets

Madopar Rapid tablets are for people who have difficulty swallowing whole tablets or who require the medicine to work quickly. They should be mixed with a quarter of a glass (at least 25-50mL) of water. The tablets will disperse into granules to give a milky-looking liquid which you should drink within 30 minutes. Remember to stir the liquid immediately before taking because the granules can settle at the bottom. The tablets do not completely dissolve.

• 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.

• Do not chew capsules or tablets.

When to take Madopar

- Madopar should be taken either 30 minutes before a meal or one hour after a meal, if possible. 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. a biscuit) or liquid. Tell your doctor if anything worries you.
- 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.

If you forget to use Madopar

Madopar should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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

If you use too much Madopar

If you think that you have used too much Madopar, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Madopar?

Things you should do

- Tell the surgeon or anaesthetist that you are taking this medicine if you are going to have surgery.
- Tell your doctor if you become pregnant whilst taking Madopar. Madopar should not be taken during pregnancy. You should use effective contraception to avoid becoming pregnant while you are being treated with 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 that Madopar is not helping your condition.
- Tell your doctor if you suffer from sleepiness or sudden onset of sleep during daily activities.
- Keep all of your appointments with your doctor so that your progress can be checked.
- Remind any doctor, dentist or pharmacist you visit that you are using Madopar.

Your doctor may perform regular tests while you are taking Madopar.

Things you should 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 any other complaints unless your doctor tells you to.
- Do not take any other medicines whether they require a prescription or not without first talking to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your medicine

- 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 as well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store Madopar in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep Madopar where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Motion or movement related: • 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 • restlessness • poor muscle tone, hiccups Stomach, bowel or urinary related: • nausea and vomiting • loss of appetite • weight gain • constipation • water retention, cramps	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
- your urine, mouth, saliva, tongue and teeth may be darker with a red tinge Skin related: - skin rash or itching - bleeding or bruising more easily Mental states or behaviour related: - changes in sex drive or hypersexuality - signs of compulsive behaviour (performing a repetitive purposeless activity) - mental changes including paranoia, depression, mania, agitation and hallucinations (seeing, feeling or hearing things that are not there) - confusion, tiredness, sleeplessness, or sudden onset of sleep episodes Infections: - frequent infections such as fever, severe chills - sore throat or mouth ulcers Other side effects: - fluctuations in the effect of Madopar known as freezing episodes. These can usually be helped by asking your doctor to adjust your dose - loss of taste	

Serious side effects

Serious side effects	What to do
Signs and symptoms of problems with your heart - palpitations or changes in the rhythm or rate of the heartbeat, chest pain, dizziness on standing up Stomach, bowel or urinary related: - diarrhoea Mental states or behaviour related: - confusion	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Madopar contains

Active ingredient (main ingredient)	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 125 tablets contain levodopa 100 mg and benserazide 25 mg. Madopar 250 tablets contain levodopa 200 mg and benserazide 50 mg. 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.
Other ingredients (inactive ingredients)	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 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 62.5 and Rapid 125 tablets contain: citric acid, starch- maize, microcrystalline cellulose and magnesium stearate.
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Do not take this medicine if you are allergic to any of these ingredients.

What Madopar looks like

There are eight Madopar products available to meet individual needs:

Madopar Capsules:

- Madopar 62.5 - AUST R 13744 - are light grey at one end and powder blue at the other end, with 'ROCHE' printed on both ends.
- Madopar 125 - AUST R 13746 - are flesh coloured at one end and powder blue at the other end, with 'ROCHE' printed on both ends.
- Madopar 250 - AUST R 13742 - are caramel coloured at one end and powder blue at the other end, with 'ROCHE' printed on both ends.
- Madopar HBS (slow release) - AUST R 13743 - are light blue at one end and dark green at the other end, with 'ROCHE' printed in red ink on both ends.

Madopar Tablets:

- Madopar 125 - AUST R 43517 - are pale red in colour, cross-scored on both sides.
- Madopar 250 - AUST R 13745 - are pale red in colour, imprinted on both sides with 'ROCHE' and a hexagon on one side crossed-scored on both sides.

Madopar Rapid Tablets:

- Madopar Rapid 62.5 - AUST R 59577 - are off-white in colour, scored on one side and printed with 'ROCHE 62.5' on the other.
- Madopar Rapid 125 - AUST R 59576 - are off-white in colour, scored on one side and printed with 'ROCHE 125' on the other.

All Madopar capsules and tablets come in bottles of 100.

Who distributes Madopar

Madopar is distributed in Australia by:
Roche Products Pty Limited
ABN 70 000 132 865
Level 8, 30-34 Hickson Road
Sydney NSW 2000

Medical enquiries: 1800 233 950

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