

## PRODOPA



Methyldopa 125mg, 250mg and 500mg Tablets

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### What is in this leaflet

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This leaflet answers some common questions about PRODOPA. It does not contain all the information available on this medicine. 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 using PRODOPA against the benefits expected it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist. Keep this leaflet. You may want to read it again.

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### What PRODOPA is used for and how it works

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Your PRODOPA tablets contain the active ingredient methyldopa.

PRODOPA is used to lower high blood pressure, also called hypertension. It works by widening blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

Your doctor may, however, prescribe PRODOPA for another reason. Ask your doctor if you have any questions about why PRODOPA has been prescribed for you.

There is no evidence that PRODOPA is addictive.

PRODOPA is available on prescription from your doctor.

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### Before you take PRODOPA

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#### ***When you must not take it***

**Do not take PRODOPA if:**

**You are allergic to methyldopa or any other ingredients listed at the end of this leaflet**

**You have liver disease such as hepatitis or cirrhosis**

**You have a past history of liver problems due to taking methyldopa**

**You are currently taking any monoamine oxidase inhibitors (MAOIs), used to treat depression and Parkinson's disease**

**You are suffering from depression**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

#### ***Before you take it***

Tell your doctor:

If you have blood problems

If you have liver problems

If you are undergoing dialysis (a procedure used to remove waste products from the blood of a person with kidney failure)

If you have phaeochromocytoma (a rare tumour of the adrenal gland)

If you are pregnant or planning to become pregnant

If you are breastfeeding or planning to breastfeed

If you or any of your immediate family suffer from Porphyria

## ***Taking other medicines***

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop, tell your doctor or pharmacist.

Medicines that may interfere with PRODOPA include:

Other medicines used to treat high blood pressure  
Monoamine oxidase inhibitors (MAOIs), medicines used to treat depression and Parkinson's disease  
Lithium, a medicine used to treat mood swings and some types of depression

These medicines may be affected by PRODOPA or may affect how well PRODOPA works. You may need different amounts of your medicines or you may need to take different medicines.

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

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## **How to take PRODOPA properly**

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### ***How much to take***

Your doctor will tell you how much PRODOPA you need to take each day. It is important that you take PRODOPA as directed by your doctor. Do not take more than the recommended dose.

The usual starting dose for adults is 250mg, taken two to three times a day. Your doctor may increase or decrease this dose, depending on how you respond to this medicine.

Elderly people over 65 years of age and people with kidney problems may need smaller doses.

For children, the starting dose is based on their weight. Your child's doctor may increase or decrease this dose, depending on their response to this medicine.

### ***How long to take it***

PRODOPA helps to control your condition but does not cure it. To properly control your condition, PRODOPA must be taken every day on a long-term basis. Continue taking PRODOPA for as long as your doctor tells you to.

### ***If you forget a dose***

If you forget a dose, just take the next dose when it is due. Do not take more than one dose at a time to make up for missed doses.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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## **While you are taking PRODOPA**

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

Tell your doctor or pharmacist that you are taking PRODOPA before you start any new medicine.

Tell your doctor if you develop a skin rash or hives, or you become pregnant while taking PRODOPA.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking PRODOPA.

If you are going to have any blood tests, tell your doctor that you are taking PRODOPA.

Do not take PRODOPA to treat any other complaints unless your doctor tells you to.

Do not stop taking PRODOPA or lower the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

Be careful getting up from a sitting or lying position. Dizziness, lightheadedness or fainting may occur when you begin to take PRODOPA, or if the dose is increased. This happens especially when you get up quickly from a sitting or lying position. Getting up slowly may help. This problem usually goes away after the first few days.

**PRODOPA may cause dizziness, drowsiness or lightheadedness in some people.** Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that PRODOPA is not affecting your performance.

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## Side effects

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

All medicines can have some unwanted 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.

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

Dizziness, lightheadedness  
Drowsiness  
Headache

These are the common and mild side effects of methyldopa, which may disappear with continued treatment. These side effects may occur at the beginning of treatment or when the dose is increased.

**Tell your doctor immediately if you experience:**

Ongoing weakness  
Fever shortly after taking PRODOPA, for example within the first 3 months  
Yellowing of the eyes or skin (jaundice)  
Darker urine than normal  
Pale stools  
Swelling of the feet or ankles  
Nightmares, feeling strange or depressed  
Signs of infection such as fever, chills, sore throat or mouth ulcers  
Bleeding or bruising more easily than normal  
Tiredness, looking pale together with being short of breath when exercising and tingling or numbness of the hands or feet  
Itchy skin rash or other skin problems  
Slow heart beat or pulse  
Worsening of angina (chest pain)

Nausea, vomiting, constipation, flatulence, diarrhoea, colitis  
Abnormal or involuntary movements of the body

**These side effects are rare but serious. You may need urgent medical attention.**

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## **In case of overdose**

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You should only take the number of tablets that you have been told.

**Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any PRODOPA by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.** Take the container of PRODOPA with you if you can.

Keep telephone numbers for these places handy.

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## **Storage conditions**

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Do not take this medicine after the expiry date shown on the label or if the packaging shows signs of tampering.

Keep your PRODOPA tablets in the container until it is time to take them.

Store below 25°C and out of reach of children. Avoid exposure to heat, light and moisture.

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

### ***Disposal***

If your doctor tells you to stop taking PRODOPA or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

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## **Product Description**

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### ***What PRODOPA tablets look like***

PRODOPA 125mg tablets are round, yellow, film-coated tablets that are marked with "MD" over "125" on one side and "G" on the other.

PRODOPA 250mg tablets are round, yellow, film-coated tablets that are marked with "MD" over "250" on one side and "G" on the other.

PRODOPA 500mg tablets are round, yellow, film-coated tablets that are marked with "MD" over "500" on one side and "G" on the other.

Each PRODOPA tablet contains the active ingredient, methyldopa.

Each PRODOPA tablet also contains the ingredients citric acid, disodium edetate, ethylcellulose, guar gum, sodium starch glycollate, colloidal silicon dioxide, magnesium stearate and the film coat Opadry Yellow.

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## **If you want to know more**

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Should you have any questions regarding this product, please contact your doctor or pharmacist.

### ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland.

Phone: (09) 579 2792

### ***Date of information***

2 February 2009  
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