HYDOPA®

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking HYDOPA?

HYDOPA contains the active ingredient methyldopa. HYDOPA is used to lower high blood pressure, which doctors call hypertension.

For more information, see Section <u>1. Why am I taking</u> <u>HYDOPA?</u> in the full CMI.

2. What should I know before I take HYDOPA?

Do not take if you have ever had an allergic reaction to methyldopa 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 <u>2. What should I know</u> <u>before I take HYDOPA?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HYDOPA and affect how it works.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I take HYDOPA?

- The dose of HYDOPA varies from patient to patient.
- Swallow the tablets whole with a glass of water or other liquid.

More instructions can be found in Section <u>4. How do I</u> <u>take HYDOPA?</u> in the full CMI.

5. What should I know while taking HYDOPA?

| Things you should do | Remind any doctor, dentist, pharmacist, or anaesthetist you visit that you are using HYDOPA. Have your blood pressure checked regularly. |
|----------------------|---|
|----------------------|---|

| | Stand up slowly when getting up to avoid dizziness in the first few days. Tell your doctor if you develop a fever. Make sure you drink enough water during exercise and hot weather. |
|-----------------------------|---|
| Things you should not do | Do not give your medicines to anyone else, even if they have the same condition as you. Do not stop taking HYDOPA or lower the dose unless advised by your doctor. |
| Driving or using machines | Be careful of driving or operating machinery until you know how HYDOPA affects you. HYDOPA may cause dizziness, light headedness, drowsiness or sleepiness. |
| Drinking alcohol | Drinking alcohol may exacerbate any dizziness and |

| | drowsiness from HYDOPA. |
|-----------------------------|--|
| Looking after your medicine | Keep HYDOPA in a cool dry place, away from moisture, heat, or sunlight where the temperature stays below 25°C. |

For more information, see Section <u>5. What should I know</u> while taking HYDOPA? in the full CMI.

6. Are there any side effects?

Less serious side effects: dizziness, weakness, lightheadedness, drowsiness, and headache. Serious side effects: fever (within the first 3 months of starting), yellowing of the skin and eyes, darker urine than normal, pale stools, swelling of limbs, nightmares or feeling strange or depressed, signs of frequent or worrying infections (e.g. fever, severe chills, sore throat, or mouth ulcers), bruising more easily than normal, signs of anemia (e.g. tiredness, shortness of breath, and looking pale), numbness/tingling/pain or weakness in your hands or feet, itchy skin rash or other skin problems, a slow heart beat or pulse, worsening of angina (chest pain), or larger breasts than normal (especially in men).

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

HYDOPA®

Active ingredient: methyldopa (as sesquihydrate)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- 1. Why am I taking HYDOPA?
- 2. What should I know before I take HYDOPA?
- 3. What if I am taking other medicines?
- 4. How do I take HYDOPA?
- 5. What should I know while taking HYDOPA?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking HYDOPA?

HYDOPA contains the active ingredient methyldopa.

HYDOPA is used to lower high blood pressure, which doctors call hypertension.

Everyone had blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure. HYDOPA helps to lower your blood pressure.

HYDOPA works by controlling impulses along certain nerve pathways and as a result, widens blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

Your doctor may have prescribed it for another purpose. If you are not sure why you are taking HYDOPA, ask your doctor.

There is no evidence that HYDOPA is addictive.

2. What should I know before I take HYDOPA?

Warnings

Do not take HYDOPA if:

• you are allergic to methyldopa (as sesquinhydrate), or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

Always check the ingredients to make sure you can take this medicine.

- you have taken HYDOPA in the past and developed liver problems
- you have certain liver diseases, such as hepatitis or cirrhosis
- you are taking with a medicine called a monoamine oxidase inhibitors (MAOIs).

MAOIs are used to treat depression and Parkinson's disease. MAOIs include moclobemide, phenelzine, and tranylcypromine.

Ask your doctor or pharmacist if you are not sure whether you are taking one of these MAOI medicines.

the expiry date on the pack has passed.

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

• the package shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking HYDOPA, talk to your doctor.

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - angina (chest pain)
 - liver problems
 - phaeochromocytoma or paraganglioma (a rare tumour of the adrenal gland, which sits near the kidney), or if you are suspected of having this
 - are undergoing dialysis (a procedure used to remove waste products from the blood of a person with kidney failure)
 - porphyria (a rare blood pigment disorder)
- take any medicines for any other condition
- have an allergy to any other medicines, or any other substances, such as foods, preservatives or dyes.

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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor will discuss the possible risks and benefits of using HYDOPA during pregnancy and breast#feeding. HYDOPA passes into breast milk.

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 should NOT be taken with HYDOPA. These include:

• MAOIs such as moclobemide, phenelzine and tranylcypromine.

Some medicines and HYDOPA may interfere with each other. These include:

- other medicines for high blood pressure
- lithium, a medicine used to treat mood swings and some types of depression
- iron supplements and multivitamins containing iron. These medicines may be affected by HYDOPA or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking HYDOPA.

4. How do I take HYDOPA?

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

- Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking any other medicines.
- Follow the instructions provided and use HYDOPA until your doctor tells you to stop.

When to take HYDOPA

- HYDOPA should be taken at the same time each day unless your doctor tells you otherwise.
- If you are taking it twice a day, take the tablets at breakfast time and dinner time – that is, about 12 hours apart.
- If you are taking it three times a day, take the tablets about 8 hours apart.
- Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you remember when to take the tablets.
- It does not matter if you take HYDOPA before or after food.

How to take HYDOPA

• Swallow the tablets whole with a glass of water.

How long to take it

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

If you forget to take HYDOPA

HYDOPA should be taken regularly at the same time each day.

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you take too much HYDOPA

If you think that you or anyone else has taken too much HYDOPA, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) for advice, 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.

If you take too much HYDOPA, you may feel dizzy, lightheaded, drowsy or you may faint. You may also experience nausea (feeling sick), vomiting, constipation, diarrhoea, gas/wind in the bowel or develop a bloated stomach.

5. What should I know while taking HYDOPA?

Things you should do

- Have your blood pressure checked when your doctor says to make sure HYDOPA is working.
- If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

You may feel light-headed or dizzy when you begin to take HYDOPA or if the dose is increased. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. The problem usually goes away after the first few days.

- If you are about to be started on any new medicine remind your doctor and pharmacist that you are taking HYDOPA.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking HYDOPA.

It may affect other medicines used during surgery.

If you need to have surgery that requires a general anaesthetic, tell your doctor or dentist that you are taking HYDOPA Your blood pressure may drop suddenly.

 If you are having blood and urine tests, tell your doctor you are taking HYDOPA.

HYDOPA may interfere with some of these tests giving incorrect results.

• If you develop fever, tell your doctor.

Your doctor may need to do some blood tests to make sure HYDOPA is not affecting your liver or blood.

 Tell your doctor if you are to have a blood transfusion, that you are taking HYDOPA or have taken it in the past few months.

HYDOPA may interfere with the tests used to decide which blood group you receive.

 Make sure you drink enough water during exercise and hot weather when you are taking HYDOPA, especially if you sweat a lot.

If you do not drink enough water while taking it, you may faint or feel lightheaded or sick. This is because your body doesn't have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.

- Since HYDOPA is meant to be taken regularly, keep a continuous supply of medicine so you don't run out, especially over weekends or on holidays.
- Visit your doctor regularly so they can check on your progress.

Your doctor may want to check your liver function and blood count, especially within the first 12 weeks of starting HYDOPA.

Call your doctor straight away if you:

- become pregnant while taking this medicine.
- are experiencing any of the serious side effects listed under Section <u>6. Are there any side effects?</u>

Things you should not do

- Do not take HYDOPA to treat any other complaints unless your doctor tells you to.
- Do not give your medicines to anyone else, even if they have the same condition as you.
- Do not stop taking HYDOPA or lower the dosage unless advised by your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how HYDOPA affects you.

HYDOPA may cause dizziness, light headedness, drowsiness or sleepiness, especially after the first few doses and if the dose is increased. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or drowsy.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or drowsiness from HYDOPA can be worse.

Looking after your medicine

• Keep your tablets in the bottle until it is time to take them. If you take the tablets out of the bottle they may not keep well.

• Store below 25°C.

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

Store it 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.

Heat and dampness can destroy some medicines.

Keep it 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.

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date.

6. Are there any side effects?

HYDOPA helps most people with high blood pressure, but it may have unwanted side effects in a few people. 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

| Less serious side effects | What to do |
|---|---|
| dizziness light-headedness drowsiness headache weakness | Speak to your doctor if you have any of these less serious side effects and they worry you. This includes the more common side effects |
| | of HYDOPA. They are usually mild and short-lived. These side effects may occur at the beginning of treatment or when the dose is increased. |

Serious side effects

| Serious side effects | What to do |
|---|--|
| fever shortly after starting to take HYDOPA, for example, within the first 3 months | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you |

| Serious side effects | What to do |
|---|---|
| yellowing of the skin and eyes, also called | notice any of these serious side effects. |
| jaundice darker urine than normal due to liver problems pale stools swelling of the feet or lower legs | The above list includes serious side effects. You may need urgent medical attention. These side effects are rare. |
| nightmares, feeling strange or depressed | |
| signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers | |
| bruising more easily than normal | |
| signs of anaemia, such as tiredness, being short of breath, and looking pale | |
| numbness, tingling, pain, or weakness in your hands or feet | |
| itchy skin rash or other skin problems | |
| a slow heart beat or pulse | |

| Serious side effects | What to do |
|---|------------|
| worsening of angina (chest pain) | |
| larger breasts than normal, especially in men | |

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 <u>www.tga.gov.au/reporting-problems</u>. 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 HYDOPA contains

| Active ingredient (main ingredient) | methyldopa (as sesquihydrate) equivalent to 250 mg of anhydrous methyldopa |
|---|--|
| Other ingredients (inactive ingredients) | citric acid disodium edetate ethylcellulose sodium starch glycollate guar gum colloidal anhydrous silica magnesium stearate Opadry Yellow OY-8462 (ID: 3116). |
| Potential allergens | sulfites and soya bean products |

Do not take this medicine if you are allergic to any of these ingredients.

What HYDOPA looks like

HYDOPA is a 10.2 mm normal convex, yellow, filmcoated tablet debossed "MD 250" on one side and "G" on the other (AUST R 69482).

Each pack contains 100 tablets.

Who distributes HYDOPA

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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