

INFORMATION FOR THE PATIENT

Pr APO-MIDODRINE Midodrine Hydrochloride Tablets

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

This leaflet is part III of a three-part "Product Monograph" published when APO-MIDODRINE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about APO-MIDODRINE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

APO-MIDODRINE is used for certain patients that have low blood pressure when in a standing position. It is used in people whose living activities are severely impaired even after other treatments are used.

What it does:

Midodrine increases blood pressure by causing blood vessels to tighten.

When it should not be used:

APO-MIDODRINE should not be taken without first consulting your doctor if you have any of the following conditions:

- High blood pressure experienced when lying down
- Severe heart disease
- Kidney disease
- Urinary difficulties
- Pheochromocytoma (a tumour of the adrenal gland that causes excess release of hormones that regulate blood pressure)
- Overactive thyroid
- Are allergic to midodrine hydrochloride or to any of the nonmedicinal ingredients listed under "What the important nonmedicinal ingredients are"

What the medicinal ingredient is:

Midodrine hydrochloride

What the important nonmedicinal ingredients are:

APO-MIDODRINE 2.5 mg and 5 mg tablets contains the following nonmedicinal ingredients: colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose and starch. APO-MIDODRINE 5 mg tablets also contain the colourant FD&C Yellow #6 Aluminum Lake 40%.

What dosage forms it comes in:

APO-MIDODRINE is available as 2.5 mg and 5 mg tablets.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Use of APO-MIDODRINE can cause a marked increase in blood pressure experienced when lying down.

BEFORE you use APO-MIDODRINE talk to your doctor or pharmacist if you:

- Have high blood pressure
- Are taking any of the medications listed in the section entitled "Interactions With This Medication"
- Have urinary difficulties

- Have an irregular heart beat
- Have low blood pressure, are diabetic or have a history of visual problems
- Have kidney or liver problems
- Are pregnant or nursing

INTERACTIONS WITH THIS MEDICATION

You should always tell your physician about all drugs you are taking or planning to take, including those obtained without a prescription.

Drugs that may interact with APO-MIDODRINE include: digitalis glycosides (e.g. digoxin, digitoxin), adrenaline-like drugs (e.g., phenylephrine, pseudoephedrine, ephedrine, phenylpropanolamine or dihydroergotamine), alpha blockers (e.g., phentolamine, prazosin, doxazosin and labetalol and steroids that cause salt-retention (e.g. fludrocortisone).

PROPER USE OF THIS MEDICATION

Usual dose:

Treatment with APO-MIDODRINE should be started under close medical supervision so that your blood pressure can be monitored carefully. The starting dose of APO-MIDODRINE is 2.5 mg 3 times daily or as directed by your doctor. The drug should be taken during daytime hours, when you are likely to be upright most often. APO-MIDODRINE should not be taken after the evening meal or less than 4 hours before bedtime.

Overdose:

Seek emergency medical attention if an overdose of this medication is suspected.

Symptoms of a midodrine overdose may include increased blood pressure (heart pounding or slower heartbeat, pounding sensation in your ears, headache or blurred vision), goose bumps, a feeling of being cold and difficulty urinating.

Missed Dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects of APO-MIDODRINE are: High blood pressure experienced when sitting or lying down; Tingling or itching of the skin, mainly of the scalp; Goose bumps; Chills; Urinary problems; Abnormal loss of strength; Dizziness; Pain in the upper area of the stomach; Hair disease; Headache; Shortness of breath; Nausea; Nervousness; Pain; Rash

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SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	High blood pressure experienced when lying down		✓	✓
Uncommon	Abnormal heartbeat		✓	✓
Uncommon	Loss of vision (Central retinal vein occlusion)		✓	✓
Uncommon	Increased dizziness/faintness		✓	✓

This is not a complete list of side effects. For any unexpected effects while taking APO-MIDODRINE, contact your doctor or pharmacist.

HOW TO STORE IT

Store away from heat and direct light. Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadrmpp@hc-sc.gc.ca

By regular mail:
Canadian Adverse Drug Reaction Monitoring Program
(CADRMP)
Health Canada
Address Locator: 0201C2
Ottawa, ON K1A 1B9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service at:

1-800-667-4708

This leaflet can also be found at: <http://www.apotex.ca/products>.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

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