

# Midodrine Hydrochloride 2.5 mg and 5 mg Tablets

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## Consumer Medicine Information (CMI) summary

### *midodrine Hydrochloride 2.5 mg and 5 mg tablets*

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#### What is in this leaflet

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This leaflet answers some common questions about Midodrine hydrochloride tablets. It does not contain all the available information.

It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Midodrine hydrochloride tablets against the benefits this medicine is expected to 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.

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#### What Midodrine hydrochloride tablets are used for

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Midodrine hydrochloride tablet is used to treat the symptoms of idiopathic orthostatic **hypotension** found in Bradbury- Eggleston or Shy-Drager syndromes. Idiopathic orthostatic hypotension is a fall in blood pressure that occurs upon rising abruptly to an upright position although it may also occur following a period of prolonged standing.

The body's nervous system is responsible for this type of hypotension. Midodrine hydrochloride is administered in those cases where the response to other therapy is not adequate.

Midodrine hydrochloride tablet is also used where hypotension is a consequence of other medical disorders such as diabetes or Parkinson's disease.

**Hypotension is low blood pressure.** It is a measure of the blood pressing on the artery walls. This pressure helps move your blood around your body. You have hypotension when your blood pressure stays lower than normal. **Midodrine hydrochloride tablet may increase your blood pressure by constricting the walls of your blood vessels.**

Your doctor may have prescribed Midodrine hydrochloride tablets for another reason.

Ask your doctor if you have any questions about why Midodrine hydrochloride tablets have been prescribed for you.

Midodrine hydrochloride tablets are a prescription only medicine.

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## **Before you take Midodrine hydrochloride tablets**

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

**Do not take Midodrine hydrochloride tablets if you have had an allergy to:**

- midodrine
- other alpha adrenergic receptor stimulants
- any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction to Midodrine hydrochloride tablets may include:

- asthma, shortness of breath, wheezing
- swelling of the face, lips, or tongue which may lead to difficulty swallowing or breathing
- rash, itching or hives
- fainting

**Do not take Midodrine hydrochloride tablets if you have any of the following medical conditions:**

- heart disease
- kidney failure
- urinary retention
- pheochromocytoma - a tumor of the adrenal glands
- thyrotoxicosis - a condition resulting from an overactive thyroid gland
- tachyarrhythmias or ventricular fibrillation - an abnormal heartbeat

**Do not take Midodrine hydrochloride tablets if you are under the age of 18 years.**

There is inadequate information about the use of Midodrine hydrochloride in children.

**Do not take Midodrine hydrochloride tablets if the packaging is torn or shows signs of tampering or if the tablets show visible signs of deterioration.**

Do not take Midodrine hydrochloride tablets after the expiry date (EXP) printed on the pack.

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

### ***Before you start taking it***

Tell your doctor or pharmacist if you are allergic to any other medicines, foods, dyes or preservatives.

Midodrine hydrochloride may cause the following medical conditions:

- **supine hypertension:** This is high blood pressure measured when lying down. It is a serious and frequent adverse reaction to Midodrine hydrochloride and, if sustained, may cause stroke, heart attack and kidney dysfunction which, individually or collectively, may be fatal. Symptoms may include palpitations, pounding in the ears, headache and blurred vision.
- **bradycardia:** This is a slow heartbeat. Symptoms may include the pulse slowing, increased dizziness, fainting and palpitations. Some medicines taken at the same time as Midodrine hydrochloride may directly or indirectly reduce heart rate such as glycosides (eg. digitalis), psychopharmacologic medicines and beta-blockers (eg. propranolol).
- **tachyarrhythmias** or ventricle fibrillation: These are both abnormal heartbeats. Midodrine hydrochloride should not be taken before these medical conditions are corrected.
- **urinary retention:** Midodrine hydrochloride may affect the bladder, leading to urine being retained. Symptoms of bladder retention are hesitancy or frequency of urination.

If any of the above symptoms occur. Stop taking Midodrine hydrochloride and see your doctor immediately.

Tell your doctor if you already **have urinary tract or bladder** problems as midodrine may affect your body's ability to eliminate medicines including midodrine itself.

Tell your doctor if you are **pregnant** or intend to become pregnant.

There is insufficient information on the use of Midodrine hydrochloride in pregnant women. Your doctor will discuss the risks and benefits of taking this medicine during pregnancy.

**Tell your doctor if you are breastfeeding or plan to breastfeed.**

It is not known if midodrine can be found in breast milk and, due to insufficient information, an alternative to breast-feeding should be used.

**Midodrine hydrochloride tablets are unlikely to produce an effect on the ability to drive or use machinery. However care should be taken until you know how this medicine affects you.**

**There is no evidence this medicine is addictive.**

#### *Taking other medicines*

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with Midodrine hydrochloride tablets. These include:

- **cardiac glycosides** such as digitalis and digoxin. These are medicines taken for heart conditions and are used to reduce heart rate. They may enhance or cause bradycardia, abnormal heart beat or may stop the small electrical impulse that travels through the heart.
- **vasoconstrictor sympathomimetic medicines** such as phenylephrine, methoxamine and dihydroergotamine. They may enhance the effects of Midodrine hydrochloride.
- **salt retaining steroids** such as fludrocortisone. You may experience supine hypertension

which may be minimised by either reducing the dose of fludrocortisone or decreasing salt intake prior to starting treatment with Midodrine hydrochloride tablets.

- **alpha adrenergic blocking agents** - Midodrine hydrochloride is an alpha adrenergic **receptor** stimulant and **blocking** agents cancel the action of Midodrine hydrochloride.

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

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## **How Midodrine hydrochloride tablets are taken**

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**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 Midodrine hydrochloride tablets you should take each day. This depends on your condition, simultaneous use of other medicines and the results of the tests carried out by your doctor in order to determine the optimal response for you. The usual starting dose is 2.5 mg, three times daily, but your doctor may have prescribed a different dose.

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

Swallow the prescribed dose of tablets with a glass of water.

### ***When to take it***

Your doctor will tell you when to take Midodrine hydrochloride tablets. You may require a higher dose in the morning and your doctor will explain your schedule. In order to reduce the possibility of supine hypertension, it is recommended that Midodrine hydrochloride tablets should not be taken after evening meals.

### ***If you forget to take it***

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 continue taking it as you would normally.

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

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

If you have trouble remembering your dose, ask your pharmacist for some hints.

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## **While you are taking Midodrine hydrochloride tablets**

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### ***Things you must do***

Tell all doctors and pharmacists who are treating you that you are taking Midodrine hydrochloride tablets. Tell your doctor if you become pregnant while taking Midodrine hydrochloride tablets.

Tell your doctor if you feel the tablets are not helping your condition

Remember to measure your blood pressure lying down and sitting up for at least a month after first taking Midodrine hydrochloride tablets and twice per week afterwards. If your blood pressure in either position increases above 180/100 mmHg, stop taking Midodrine hydrochloride and see your doctor immediately.

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

### ***Things you must not do***

Do not stop taking Midodrine hydrochloride tablets 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 Midodrine hydrochloride tablets to anyone else even if they have the same condition as you. Do not use Midodrine hydrochloride tablets to treat other complaints unless your doctor says to.

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

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Midodrine hydrochloride tablets.**

Midodrine hydrochloride helps most people but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious. 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:**

- nausea and vomiting
- stomach discomfort
- diarrhoea
- piloerection - hair standing on end

- abnormal sensations
- chills

**Tell your doctor immediately if you notice the following:**

- palpitations
- pounding in the ears
- headache
- blurred vision
- chest pain
- itchy skin
- hesitancy during urination and changes in frequency of urination
- painful urination
- weakness
- tremor
- depression
- flushing
- asthma, shortness of breath, wheezing
- swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing
- rash, itching or hives
- fainting

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

This is not a complete list of all possible side effects. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you do not understand anything in this list.

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

## **Overdose**

Immediately telephone your doctor or National Poisons Information Centre (New Zealand: telephone 0800 POISON or 0800 764 766; Australia: 13 11 26) for advice or go to your nearest Casualty Department (Accident and Emergency Centre) if you think that you or anyone else may have taken too many Midodrine hydrochloride tablets. Do this even if there are no signs of discomfort or poisoning.

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## Storage

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**Keep your tablets in the original container and protect from light until it is time to take them.**

If you take the medicine out of its container, it may not keep well.

**Keep Midodrine hydrochloride 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 windowsills.**

Heat and dampness can destroy some medicines.

**Keep Midodrine hydrochloride where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

If your doctor tells you to stop taking Midodrine hydrochloride tablets, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets left over.

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## Product description

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### *What it looks like*

Midodrine hydrochloride tablets MEDSURGE are available in two strengths.

**2.5 mg tablets:** White coloured round shaped, flat tablets debossed with 'M2' on one side and score line on another side.

Midodrine hydrochloride 2.5 mg tablets MEDSURGE come in blister packs of 10s, 14s, 20s, 28s, 30s, 56s, 60s, 84s, 90s, 100s, 112s tablets.

**5 mg tablets:** Orange coloured round shaped, flat tablets debossed with "M5" on one side and score line on another side.

Midodrine hydrochloride 5 mg tablets MEDSURGE come in blister packs of 10s, 14s, 20s, 28s, 30s, 56s, 60s, 84s, 90s, 100s, 112s tablets.

Not all strengths and packs may be marketed.

### *Other ingredients*

**2.5 mg tablets:** magnesium stearate, microcrystalline cellulose, purified talc, colloidal anhydrous silica and maize starch.

**5 mg tablets:** magnesium stearate, microcrystalline cellulose, purified talc, colloidal anhydrous silica, maize starch and sunset yellow lake.

***New Zealand Sponsor***

Medsurge Pharma Limited

PO Box 331054

Takapuna

Auckland 0622

Telephone: 0800 788 261

**Marketed and distributed by Medsurge Healthcare Pty Ltd.**

Telephone: 1300 788 261

Website: [www.medsurgehc.com](http://www.medsurgehc.com)

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