# Midodrine hydrochloride (Tillomed) 2.5 mg and 5 mg tablets

Midodrine hydrochloride 2.5 mg and 5 mg tablets

# What is in this leaflet

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 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.

# What Midodrine hydrochloride is used for

Midodrine 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 is administered in those cases where the response to other therapy is not adequate.

Midodrine 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 may increase your blood pressure by constricting the walls of your blood vessels.** 

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

# Before you use Midodrine hydrochloride

### When you must not take it

# Do not take 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 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 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 if you are under the age of 18 years.

There is inadequate information about the use of midodrine in children.

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

Do not take Midodrine hydrochloride 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 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 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 this medicine 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 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 breastfeeding should be used.

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

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

# How to use

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 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 the 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 not to take the tablets 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.

# While you are using Midodrine hydrochloride

# Things you must do

Tell all doctors and pharmacists who are treating you that you are taking midodrine hydrochloride. 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 the tablets, and twice per week afterwards. If your blood pressure in either position increases above 180/100 mmHg, stop taking the tablets 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 the 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 this medicine to anyone else, even if they have the same condition as you. Do not use Midodrine hydrochloride 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.

# In case of overdose

# If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to the Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much.

Do this even if there are no signs of discomfort or poisoning.

# **Side Effects**

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

Midodrine 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 inthe ears
- headache
- blurred vision
- chest pain
- itchy skin
- hesitancy during urination and changes infrequency 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.

# After using Midodrine hydrochloride

### Storage

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 tablets in a cool dry place where the temperature stays below 25°C. Do not store them, or any other medicine, in a bathroom or near a sink.

Do not leave them in the car or on windowsills.

Heat and dampness can destroy some medicines.

Store all medicines where children cannot reach them.

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 this medicine, or it has passed its expiry date, ask your pharmacist what to do with any tablets left over.

# **Product description**

#### What it looks like

**2.5 mg tablet:** White to off-white, round, scored tablets debossed with 'H' above the score and 'P' below the score on one side and '504' on the other side.

Blister packs of 30, 90 and 100 tablets.

**5 mg tablet:** Light orange coloured, round, scored debossed with 'H' above the score and 'P' below the score on one side and '505' on the other side.

Blister packs of 100 tablets.

Not all strengths and pack sizes may be marketed.

# Ingredients

#### Active ingredient:

- 2.5 mg tablet: 2.5 mg midodrine hydrochloride
- 5 mg tablet: 5 mg midodrine hydrochloride

# Inactive ingredients:

- 2.5 mg tablet: hydrophobic colloidal anhydrous silica, microcrystalline cellulose, pregelatinized starch, magnesium stearate
- 5 mg tablet: hydrophobic colloidal anhydrous silica, microcrystalline cellulose, pregelatinized starch, magnesium stearate, and Pigment blend PB- 530018 orange (consists of sunset yellow FCF-Lake and pregelatinized starch).

# **Sponsor Details**

Midodrine hydrochloride is supplied in New Zealand by:

Max Health Ltd PO Box 44452 Pt Chevalier Auckland 1246 New Zealand.

Telephone: (09) 815 2664.

# **Date of Preparation**

This leaflet was prepared on 8 May 2025.