PACKAGE LEAFLET

Package leaflet: Information for the patient

Midodrine Tillomed 2.5 mg tablets

Midodrine Tillomed 5 mg tablets

midodrine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Midodrine Tillomed is and what it is used for

Midodrine Tillomed contains the active ingredient midodrine hydrochloride, which acts on the blood vessels via the sympathetic nervous system to correct imbalances of blood distribution, such as preventing too much blood pooling in the legs when standing up.

Midodrine Tillomed, is used in adults to stop the fall in your blood pressure as a result of your sympathetic nervous system not working correctly. This should help to relieve the symptoms which you might be suffering from such as dizziness, fainting, blurred vision and weakness when you sit or stand up.

2. What you need to know before you take Midodrine Tillomed

Do not take Midodrine Tillomed:

- if you are allergic to midodrine hydrochloride or any of the other ingredients of this medicine (listed in section 6);
- if you have high blood pressure (hypertension) or a form of low blood pressure known to cause fainting (vasovagal hypotension);
- if you have severe heart disease or heart failure;
- if you have a high level of thyroid hormones in the blood (thyrotoxicosis), an overactive thyroid (hyperthyroidism);
- if you have an untreated tumour of the adrenal gland (phaeochromocytoma);

- if you have severe kidney disorders;
- if you have an enlarged prostate (men only);
- if you have poor vision as a result of diabetes;
- if you have difficulty urinating;
- if you have increased pressure in the eye (glaucoma)
- if you have a narrowing of blood vessels that reduces the blood supply to the heart

Warnings and precautions

Talk to your doctor or pharmacist before taking Midodrine Tillomed if you have been told you have high blood pressure when you lie down. If this applies to you then:

Regular monitoring of your blood pressure when you are lying down and when you are standing up will be required as there may be a risk of your blood pressure rising when you lie down, for example, at night. If your blood pressure does go up when you lie down and reducing the dose does not correct the problem, then treatment with this medicine must be stopped.

It is important that you do not take this medicine late in the evening. Take your last daily dose at least 4 hours before you go to bed. By keeping your head elevated at night the potential risk of your blood pressure rising when you lie down is reduced. You should be monitored by your doctor for possible secondary effects of high blood pressure.

Also talk to your doctor if you:

- have a serious disorder of the nervous system (autonomic nervous system disorder), since taking this medicine may lead to a further drop in blood pressure when you stand up. If this occurs, further treatment with this medicine should be stopped.
- suffer from problem with your blood circulation, especially if you have symptoms such as pain or cramps in the stomach after eating, or pain or cramps in the leg while walking.

You should have your kidney function, liver function and blood pressure checked by your doctor before you start using this medicine. During treatment with this medicine, your blood pressure will be checked from time to time, and if necessary, your dose adjusted.

It is important that you immediately report symptoms related to high blood pressure, such as elevated heart rate, headache and blurred vision. Your doctor will then decide whether to adjust dosage or discontinue your treatment with Midodrine.

If any of the warnings apply to you, or have in the past, talk to your doctor.

Children and adolescents

Do not give this medicine to children and adolescents under the age of 18 because the safety and efficacy of Midodrine tablets in this age group have not been established.

Other medicines and Midodrine Tillomed

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

In particular, tell your doctor or pharmacist if you are taking:

- perphenazine (used to treat mental disorders), amiodarone (used to treat a fast or irregular heartbeat), metoclopramide (an anti-sickness medicine) because midodrine may increase their effects
- concomitant use of midodrine with sympathomimetic agents (medicines that have a stimulating effect on certain parts of the nervous system) and other vasoconstrictors (medicines that narrow blood vessels) may cause a large increase in blood pressure:
  - decongestants
  - some appetite suppressants
  - other medicines which cause high blood pressure (hypertension) e.g. methyldopa
  - tricyclic antidepressants and Monoamine Oxidase Inhibitors (MAOIs) (both used to treat depression)
  - antihistamines (used to treat allergies)
  - thyroid hormones (used when the thyroid is not working properly)
- prazosin and phentolamine (medicines used to treat heart disorders) because the effect of midodrine is blocked by these medicines
- digitalis preparations or other glycosides (medicines used to treat heart disorders) because concomitant use with this medicine may lead to cardiac dysfunction
- corticosteroids, such as fludrocortisone acetate (an anti-inflammatory medicine) because this medicine may increase its effect
- medicines which directly or indirectly reduce your heart rate because if this medicine is combined with these medicines, it is advisable that your doctor closely monitors you.

Midodrine Tillomed with food and drink

You can take these tablets with or without food.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Midodrine Tillomed is not recommended during pregnancy and in women of childbearing potential not using contraception.

If you get pregnant during treatment with Midodrine Tillomed, you must stop the treatment immediately once pregnancy is confirmed.

Breast-feeding

It is unknown whether midodrine is excreted in breast milk. A risk to the newborn/infant cannot be excluded. Midodrine Tillomed should not be taken whilst breast-feeding.

Driving and using machines

Midodrine tablets may make you feel dizzy or lightheaded; if this happens to you, do not drive or use machinery and ask your doctor for advice.

Midodrine Tillomed 5 mg tablets contains Sunset Yellow FCF (E110)

Midodrine Tillomed 5 mg tablets contain Sunset Yellow FCF (E110), which may cause allergic reactions.

3. How to take Midodrine Tillomed

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Swallow the tablet whole with a drink of water
- The tablet can be divided into equal doses
- You should take your last dose of Midodrine Tillomed at least four hours before bedtime. This is because midodrine tablets can cause high blood pressure if you are lying down for any period of time (for example, sleeping). Elevating your head at night reduces the potential risk of high blood pressure when you lie down.

Adults and the elderly:

The usual initial dose is 2.5 mg (1 tablet of 2.5 mg) taken 2 to 3 times a day. Your doctor may increase this dose each week until the best effect is seen. Most people do not need more than 30 mg a day. You should take the tablets during the daytime, when you are upright, at intervals of 3-4 hours.

Use in children

These tablets should not be given to children.

Special patient groups:

- If you are elderly, it is recommended that the initial dose should be small and that dosage is increased with caution
- If you have severe kidney problems or severe kidney disease, you should not take Midodrine Tillomed
- If you have liver problems, you should consult your doctor. The safety of midodrine in patients with liver problems has not been established.

If you take more Midodrine Tillomed than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose include: goosebumps, feeling of coldness, urgent desire to urinate, high blood pressure (hypertension) and slow heart rate (bradycardia).

If you forget to take Midodrine Tillomed

Take it as soon as you remember, unless it is time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Midodrine Tillomed

There will be no sudden drop in your blood pressure. Always talk to your doctor if you are considering stopping taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness

The following side effects may occur:

Very common side effects (may affect more than 1 in 10 people):

- goosebumps
- pain when urinating

Common side effects (may affect up to 1 in 10 people):

- tingling and itching
- increased blood pressure when lying down (daily doses above 30mg)
- nausea (feeling sick), vomiting (being sick)
- inflammation of the lining inside the mouth
- heartburn
- chills
- rash
- itching (mainly of the scalp)
- flushing
- difficulty urinating

Uncommon side effects (may affect up to 1 in 100 people):

- sleep disturbances including difficulty sleeping
- headaches
- restlessness, excitability, irritability

- slowed heart rate
- increased blood pressure when lying down (daily doses up to 7.5mg)
- stomach pain
- urge to urinate

Rare side effects (may affect up to 1 in 1000 people):

- dizziness or lightheadedness
- problems with vision
- rapid heartbeat, palpitations, irregular heart rhythm, chest pain
- stroke
- abnormal liver function including an increase in the number of liver enzymes

Not known (frequency cannot be estimated from the available data):

- anxiety
- feelings of confusion
- increased tear production
- diarrhoea

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA pharmacovigilance
Website: www.hpra.ie
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Midodrine Tillomed

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.
- For HDPE bottle pack: This medicinal product does not require any special storage condition.
  For blister pack: Store below 25^0C.
- Shelf life for HDPE bottle is 100 days after first opening.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Midodrine Tillomed contains

The active substance is Midodrine hydrochloride. Each tablet contains 2.5 mg or 5mg Midodrine hydrochloride.

The other ingredients are:

For Midodrine Tillomed 2.5 mg tablets

Hydrophobic colloidal anhydrous silica

Microcrystalline cellulose

Pregelatinized starch
Magnesium stearate

For Midodrine Tillomed 5 mg tablets

Hydrophobic colloidal anhydrous silica

Microcrystalline cellulose

Pregelatinized starch
Magnesium stearate
Sunset Yellow FCF lake aluminium (E110)

What Midodrine Tillomed looks like and contents of the pack

Midodrine 2.5 mg Tablets

Midodrine Tillomed 2.5mg tablets are 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. The diameter of the tablet is 7.10 mm.

The tablets are available in pack sizes containing 30 x 1, 90 x 1 and 100 x 1 tablets in PVC/PVDC/Aluminium perforated unit dose blisters.

They are also available in High Density Polyethylene (HDPE) bottle pack with 100 tablets.

Midodrine 5 mg Tablets

Midodrine Tillomed 5 mg tablets are light orange coloured, round, scored tablets debossed with 'H' above the score and 'P' below the score on one side and '505' on the other side. The diameter of the tablet is 7.10 mm.

The tablets are available in pack sizes containing 100 x 1 tablets in PVC/PVDC/Aluminium perforated unit dose blisters.
They are also available in High Density Polyethylene (HDPE) bottle pack with 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Tillomed Pharma GmbH
Mittelstraße 5/5a
12529 Schönefeld
Germany

Manufacturer

MIAS Pharma Limited
Suite 2, Stafford House
Strand Road
Portmarnock
Co. Dublin, Ireland

Tillomed Malta Limited
Malta Life Sciences Park,
LS2.01.06 Industrial Estate,
San Gwann, SGN 3000, Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Country	**Product name**
Ireland	Midodrine Tillomed 2.5 mg and 5 mg Tablets
France	Midodrine Tillomed 2,5 mg und 5 mg,comprimé sécable
Cyprus	Midodrine Tillomed 2.5 mg & 5 mg δισκία
Greece	MIDODRINE TILLOMED
Denmark	Midodrine Tillomed 2.5 mg & 5 mg tabletter
Sweden	Midodrine Tillomed 2.5 mg & 5 mg tabletter
Finland	Midodrine Tillomed 2.5 mg & 5 mg tabletit
Norway	Midodrine Tillomed 2.5 mg & 5 mg tabletter

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