

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**Midodrine Hydrochloride Morningside 2.5 mg
Tablets**

Active ingredient

Each tablet contains 2.5 mg midodrine hydrochloride

Inactive ingredients and allergens: See section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Midodrine Hydrochloride Morningside 2.5 mg is indicated in adults for the treatment of severe

orthostatic hypotension due to autonomic nervous system dysfunction, when other corrective methods have been ruled out and other forms of treatment are inadequate.

Therapeutic group: adrenergic and dopaminergic agents

2. Before using this medicine

Do not use this medicine if you:

- are sensitive (allergic) to midodrine hydrochloride or to any of the other ingredients in this medicine (listed in section 6)
- have high blood pressure
- have a slow pulse
- have difficulty urinating
- have certain forms of cardiovascular disease
- have elevated pressure in the eye (glaucoma) or poor vision as a result of diabetes
- have an overactive thyroid gland
- have hormonal disorders caused by a tumour in the adrenal medulla (pheochromocytoma)
- have a severe kidney disease
- have an enlarged prostate
- are breastfeeding

Special warnings about using this medicine

Before treatment with Midodrine Hydrochloride Morningside 2.5 mg, tell your doctor if:

You have been told that you have high blood pressure when you lie down. If this applies to you:

- 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 indeed rises when you lie down, and reducing the dosage does not correct this 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 bedtime. By keeping your head elevated at night, the potential risk of your blood pressure rising when you lie down is reduced.

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 problems with your blood circulation, especially if you have symptoms such as abdominal pain or cramps after eating, or pain or cramps in the legs while walking.
- suffer from a disease of the prostate, since passing urine may be difficult when taking this medicine.

It is important that you immediately report symptoms related to high blood pressure, such as chest pain, palpitations, shortness of breath, elevated heart rate, headache and blurred vision. Your doctor will then decide whether to adjust the dosage or discontinue your treatment with Midodrine Hydrochloride Morningside 2.5 mg.

If any of the warnings apply to you, or have applied 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 hydrochloride in this age group have not been established.

Tests and follow-up

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

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.

In particular, if you are taking any of the following medicines; concomitant use with these medicines may cause a large increase in blood pressure:

- reserpine and guanethidine (medicines used to reduce blood pressure)
- antihistamines (used to treat allergies)
- hormones for the thyroid (used when the thyroid is not working properly)
- tricyclic antidepressants and monoamine oxidase (MAO) inhibitors (both used to treat depression)
- other vasoconstrictors (medicines that narrow blood vessels), or sympathomimetic agents (medicines that have a stimulating effect on certain parts of the nervous system)
- prazosin and phentolamine (medicines used to treat heart disease), because the effect of this medicine is blocked by these medicines
- digitalis preparations (medicines used to treat heart disease), because concomitant use with this medicine may lead to cardiac dysfunction
- corticosteroids, such as fludrocortisone acetate (an anti-inflammatory medicine), because these medicines may increase the effect of this medicine
- medicines which directly or indirectly reduce the heart rate, because if this medicine is combined with these medicines, it is advisable that your doctor closely monitors your condition

Using this medicine and food

Midodrine Hydrochloride Morningside 2.5 mg may be taken with food.

Pregnancy and breast-feeding

Pregnancy

Using this medicine during pregnancy or in a woman of childbearing potential not using contraception is not recommended. Tell your doctor if you are pregnant, or want to become pregnant while you are being treated with this medicine.

Breast-feeding

Do not use this medicine while breast-feeding.

Driving and using machines

This medicine should not affect your ability to drive or use machines. However, you must be careful if dizziness or light-headedness occurs after taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:

The recommended starting dosage is normally one tablet of 2.5 mg, three times a day. This dosage can be increased weekly up to four 2.5 mg tablets (10 mg) three times a day, which is the usual maintenance dose of 30 mg per day. The recommended total daily dosage should be spread evenly into three doses per day.

Do not exceed the recommended dose.

Treatment duration

Your doctor will decide about your dosage and tell you how long you should take this medicine. The treatment is usually long-term.

Method of administration

Swallow the tablets with water.

To make swallowing easier, if necessary, the tablet can be split for immediate use. Swallow both halves together immediately after splitting. There is no information regarding tablet crushing/chewing.

Avoid taking this medicine in the late evening. The last dose should be taken at least 4 hours before bedtime. Elevating your head at night reduces the potential risk of high blood pressure when you lie down.

More information can be found in the section “Special warnings about using this medicine” in this leaflet.

If you have accidentally taken a higher dose, contact your doctor or pharmacist immediately.

Taking too much of this medicine may cause:

- high blood pressure (hypertension) e.g. palpitations, shortness of breath, chest pain, headache and blurred vision
- slow heart rhythm (bradycardia)
- difficulty urinating
- goosebumps
- feeling of coldness

If you forget to take the medicine

If you forget to take a dose of the medicine, take your next dose at the usual time and then keep taking your medicine as your doctor has told you. Do not take a double dose of the medicine to make up for a forgotten dose, because this will increase the risk of high blood pressure when you lie down.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

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

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Midodrine Hydrochloride Morningside 2.5 mg may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Very common side effects (may affect more than 1 in 10 people)
goosebumps, itching of the scalp and pain when urinating.

Common side effects (may affect more than 1 in 100 but less than 1 in 10 people)
tingling and itching, increased blood pressure when lying down, headache, nausea, heartburn, inflammation of the lining inside the mouth, flushing, rash, chills and difficulty urinating.

Uncommon side effects (may affect more than 1 in 1,000 but less than 1 in 100 people)
sleep disturbances, including difficulty sleeping, restlessness, agitation and irritability, slow heart rate and urge to urinate.

Rare side effects (may affect more than 1 in 10,000 but less than 1 in 1,000 people)
palpitations, rapid heartbeat, abnormal liver function, including an increase in the levels of liver enzymes.

Side effects of unknown frequency (the frequency cannot be estimated from the available data)
abdominal pain, vomiting, diarrhoea, anxiety, feelings of confusion.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package and blister. The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25°C.

- Do not throw away the medicine via wastewater or household waste. Ask the pharmacist how to throw away this medicine (medicines you no longer use). These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

microcrystalline cellulose, maize starch, silica colloidal anhydrous, talc, magnesium stearate

What the medicine looks like and contents of the pack:

Midodrine Hydrochloride Morningside 2.5 mg are round, white, flat tablets with M2 debossed on one side and a score line on the other side.

The tablets are supplied in blisters and are available in packs of 7, 10, 14, 20, 28, 30, 56, 60, 84, 90, 100 or 112 tablets.

Not all pack sizes may be marketed.

Registration holder's name and address: Trustpharm Ltd., 50 Hakishon St., Tel Aviv.

Manufacturer's name and address:

Apex Laboratories Private Ltd.,
C6, C7 & A8 SIDCO Pharmaceutical Complex Alathur, Chengalpet District
Tamil Nadu IN-603 110, India

For:

Morningside Healthcare Ltd, Unit C, Harcourt Way, Leicester, LE19 1WP, UK

Revised in August 2024.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 170-54-36873-99