

PACKAGE LEAFLET

Package leaflet: Information for the patient

Midodrine 2.5 mg & 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 is and what it is used for
2. What you need to know before you take Midodrine
3. How to take Midodrine
4. Possible side effects
5. How to store Midodrine
6. Contents of the pack and other information

1. What Midodrine is and what it is used for

Midodrine contain 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 Tablets are used 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 such as dizziness, fainting, blurred vision and weakness when you sit or stand up.

2. What you need to know before you take Midodrine

Do not take Midodrine:

- if you are allergic to midodrine hydrochloride or any of the other ingredients of this medicine (listed in section 6);
- if you have tumour near the kidney, known as phaeochromocytoma;
- if you have elevated eye pressure (narrow angle glaucoma);
- if you have thyroid gland problems called thyrotoxicosis or hyperthyroidism i.e. overactive thyroid;
- if you suffer from high blood pressure or a form of low blood pressure known as vasovagal hypotension;
- if you have some types of heart or blood vessel disease;
- if you have inflammation of the kidneys, kidney disease, poor kidney function or if you are having problems passing urine
- if you have damage to the retina in your eye as a result of diabetes (known as proliferative diabetic retinopathy)

Men only:

- if you have an enlarged prostate that causes problems emptying your bladder.

Warnings and precautions

Talk to your doctor or pharmacist before taking Midodrine if you have:

- any kidney problems
- had a stroke in the past or been told that you are at risk of a stroke
- any heart problems

Your blood pressure will be monitored before starting, and during, treatment. If you experience any chest pain, palpitations, shortness of breath, headache, blurred vision, pulse slowing, increased dizziness or faintness during treatment, STOP taking the product and seek medical help immediately.

Taking Midodrine with other medicines

Please tell your doctor if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

Particularly if you are taking:

- high blood pressure medicines e.g. alpha blockers or beta blockers
- glycosides to increase the force of your heartbeat e.g. digitalis
- tricyclic antidepressants for depression or monoamine oxidase inhibitors (MAOIs)
- amiodarone (used to control heart arrhythmias). Midodrine may increase the effect of this medicine
- metoclopramide (used to stop you feeling and being sick). Midodrine may increase the effect of this medicine
- phenothiazines and atypical antipsychotics for schizophrenia or psychosis
- antihistamines (medicines to treat allergies)
- appetite suppressants
- nasal/ sinus congestion relievers, especially those purchased without a prescription
- thyroid hormones
- steroids (e.g. fludrocortisone). In combination with Midodrine, steroids may increase the risk of eye problems or a high blood pressure whilst lying down. (These medicines are sometimes used together with Midodrine, and your doctor may have prescribed this combination for you)
- Ergot alkaloid, medicines used to treat migraines and Parkinsons.

Taking Midodrine with food and drink

You can take these tablets with or without food.

Pregnancy and breastfeeding

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

As safe use during pregnancy has not been established, Midodrine is not recommended. If you become pregnant whilst being treated with Midodrine, you must stop taking this medicine immediately.

Midodrine is not recommended during breastfeeding unless advised to by a doctor.

Driving and using machinery

Midodrine may make you feel dizzy or drowsy. If this happens to you, do not drive a vehicle or operate any tools or machinery during treatment.

Important information about some of the ingredients of Midodrine 5 mg tablets

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

3. How to take Midodrine

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 water
- Midodrine can be taken with meals

- You should take your last dose of Midodrine at least four hours before bedtime. This is because Midodrine can cause high blood pressure if you are lying down for any period of time (e.g. sleeping)
- The tablet can be divided into equal doses.

Adults and the Elderly

The usual starting dose is 2.5 mg taken 2 to 3 times daily. Your doctor may increase this dose each week until the best effect is seen.

The maximum daily dose is 30 mg.

Children

Do not give this medicine to children under the age of 18 because the safety and efficacy has not been established.

Patients with renal disorders

Midodrine should not be administered in patients with severe kidney disorders.

Patients with hepatic impairment

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 tablets than you should

If you have taken more Midodrine tablets than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet with you.

Symptoms of overdose include: high blood pressure, feeling cold, urgent desire to urinate, slow heartbeat and “goose bumps”.

If you forget to take Midodrine

If you forget to take a dose, take your next dose at the usual time and then keep taking your medicine as told by your doctor. Do not take a double dose to make up for a missed dose.

If you stop taking Midodrine

Do not stop taking these tablets without talking to your doctor first.

Contact your doctor or pharmacist if you have any further questions on the use of this medicinal product.

4. Possible side effects

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

STOP taking Midodrine and seek medical advice immediately if you experience any of the following signs of an allergic reaction:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

The following side effects may occur:

Very common: may affect more than 1 in 10 people:

- goose bumps
- difficulty/pain in urination

Common: may affect up to 1 in 10 people:

- tingling sensation of the skin (“pins and needles”)
- rash, itching (particularly of the scalp)
- chills
- flushing
- high blood pressure when lying down at daily doses of more than 30 mg (this might cause

- headaches, blurred vision, a ‘pounding’ heartbeat, chest pain or shortness of breath)
- nausea, vomiting, indigestion, sore mouth
- inflammation of mucous membrane
- inability to pass urine

Uncommon: may affect up to 1 in 100 people:

- insomnia and problems in sleeping
- headaches, restlessness, irritability, excitability
- slowing of pulse
- high blood pressure when lying down at daily doses of up to 7.5 mg
- stomach pain
- sudden urge to urinate

Rare: may affect up to 1 in 1000 people:

- dizziness or lightheadedness
- visual disturbances
- fast or irregular heartbeat, chest pain
- stroke
- increased liver enzymes (detected in blood test)

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

- anxiety
- confusion
- increased tear production
- diarrhoea

Midodrine can cause high blood pressure whilst lying down, particularly if the last dose of the day is taken too close to bedtime. This might cause headaches, blurred vision, a “pounding” heartbeat, chest pain or shortness of breath. If these occur when you lie down or go to bed, tell your doctor. This is very important as, rarely, strokes have occurred.

If you are using Midodrine in combination with other medicines that raise blood pressure e.g. fludrocortisone, and you find that your eyes are hurting, you experience visual disturbances (blurred vision) or you have a headache, especially behind the eye, you should tell your doctor.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Midodrine

- Keep this medicine out of the sight and reach of children.
- For HDPE bottle pack: This medicinal product does not require any special storage condition. For blister pack: Store below 25⁰C
- 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.
- 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 contains

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

The other ingredients are:

For both tablets:

Hydrophobic colloidal anhydrous silica
Microcrystalline cellulose
Pregelatinized starch
Magnesium stearate

For Midodrine 5 mg tablets only:

Sunset yellow FCF-Lake (E110)

What Midodrine looks like and contents of the pack

Midodrine 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 \pm 0.2 mm.

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

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

Midodrine 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 \pm 0.2 mm.

The tablets are available in pack sizes containing 100 x 1 tablets in PVC/PVDC/Aluminium and OPA/Alu/PVC/Alu 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

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