

Package leaflet: Information for the user

Midon[®] 2.5 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 Midon Tablets are and what they are used for
2. What you need to know before you take Midon Tablets
3. How to take Midon Tablets
4. Possible side effects
5. How to store Midon Tablets
6. Contents of the pack and other information

1. What Midon tablets are and what they are used for

Midon Tablets 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.

Midon 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 Midon tablets

Do NOT take the tablets if you:

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

Men only:

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

You should take your last dose of Midon Tablets at least four hours before bedtime. This is because Midon Tablets can cause high blood pressure if you are lying down for any period of time (for example, sleeping or sunbathing).

Take special care

Talk to your doctor before taking these tablets 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 other medicines

Please tell your doctor if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription, but particularly if you are taking:

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

Taking Midon Tablets with food and drink.

You can take these tablets with or without food.

Pregnancy and breast-feeding

Safe use during pregnancy and breastfeeding has not been established.

Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant, or if you are breast-feeding. Midon Tablets should not be taken by pregnant or breast-feeding women unless advised to by a doctor.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy, or if you are breast-feeding.

Driving and using machinery

Midon Tablets may make you feel dizzy or light headed; if this happens to you, do not drive or use machinery and ask your doctor for advice.

3. How to take Midon tablets

Always take the tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure about the dose you should take.

- Swallow the tablet whole with a drink of water
- You should take your last dose of Midon Tablets at least four hours before bedtime. This is because Midon Tablets can cause high blood pressure if you are lying down for any period of time (for example, sleeping or sunbathing).

Adults and the Elderly:

The usual starting dose is 2.5 mg (1 tablet of 2.5 mg) taken 2-3 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.

Children:

These tablets should not be given to children.

Special patient groups:

- If you have severe kidney problems or severe kidney disease, you should not take Midon.
- If you have liver problems, you should consult your doctor. The safety of Midon in patients with liver problems has not been established.

If you take more tablets than you should

If you have taken more tablets than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the bottle with you. Symptoms of overdose include hairs standing on end, sensation of coldness, an urgent desire to empty the bladder, slow heart beat and high blood pressure.

If you forget to take a dose

If it is more than half-way to your next dose, leave out the missed dose completely and continue with the next dose at the normal time it is due. Remember that you should not take your last dose of the day less than four hours before bedtime. Do not take a double dose to make up for a missed dose.

If you stop taking the tablets

Do not stop taking these tablets without asking your doctor first.

4. Possible side effects

Like all medicines, Midon Tablets can cause side effects, although not everybody gets them.

STOP taking Midon Tablets and **seek medical help immediately** if you have any of the following which may be 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 (affecting more than 1 in 10 users)

- hairs standing on end
- pain on passing urine

Common (affecting more than 1 in 100 users)

- at daily doses of more than 30 mg, high blood pressure when lying down (this might cause headaches, blurred vision, a "pounding" heartbeat, chest pain or shortness of breath)
- nausea, vomiting, indigestion, sore mouth
- chills
- rash, itching (particularly of the scalp), flushing
- inability to pass urine
- 'pins and needles'

Uncommon (affecting more than 1 in 1,000 users)

- insomnia and problems in sleeping
- headache, restlessness, excitability, irritability
- slow pulse rate
- at daily doses of up to 7.5 mg, high blood pressure when lying down
- stomach pain
- urgent need to urinate

Rare (affecting more than 1 in 10,000 users)

- dizziness or lightheadedness
- visual disturbances
- fast or irregular heartbeat, palpitations, chest pain,
- stroke
- abnormal liver function (detected in blood tests)

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

- anxiety
- feeling confused
- increased tear production
- diarrhoea

Midon Tablets 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. Your

doctor may adjust your dose of Midon Tablets, or recommend that you raise the head of your bed.

If you are using Midon Tablets in combination with other medicines that raise blood pressure, for example fludrocortisone, and you find that:

- your eyes are hurting or 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Midon tablets

Keep this medicine out of the sight and reach of children. Do not store above 25 °C.

Store in the original package in order to protect from moisture and light.

Do not use this medicine after the expiry date which is stated on the carton and 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 Midon Tablets contain:

The active substance is midodrine hydrochloride. Each tablet contains 2.5 mg midodrine hydrochloride.

The other ingredients in the product imported from Germany and Bulgaria are: colloidal anhydrous silica, microcrystalline cellulose, maize starch, talc, magnesium stearate.

The other ingredients in the product imported from Italy are: colloidal anhydrous silica, microcrystalline cellulose, starch, talc, magnesium stearate.

What Midon Tablets look like and contents of the pack

Midon 2.5 mg Tablets are white, round, biplanar tablets with a bevelled edge, scored on one side with 'GU' above and '2.5' below the score or Round, white, tablets. Scored on one side with 'Gutron' and a star symbol on the other side.

The tablets are provided in packs of 90 or 100 tablets. Not all pack sizes may be marketed.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland

Manufacturer

Takeda Austria GmbH, St. Peter Strasse 25, A-4020 Linz, Austria or Takeda Pharma A/S, Langebjerg 1, DK-4000 Roskilde, Denmark or Takeda GmbH Plant Oranienburg, Lehnitzstr. 70 – 98, DE-16515 Oranienburg, Germany.

Parallel Product Authorisation Number: PPA0465/276/001

Midon is a registered trademark of Nycomed Austria GmbH

Date of leaflet preparation by PCO Manufacturing: November 2018