

Package leaflet: Information for the user

Midodrin Evolan 2.5 mg tablets Midodrin Evolan 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Content of the pack and other information

1. What <Invented name> is and what it is used for

The name of your medicine is <Invented name>. It contains the substance midodrine hydrochloride. This belongs to a group of medicines called adrenergic and dopaminergic agents. Midodrine hydrochloride is a medicine that raises your blood pressure and is used to treat certain severe forms of low blood pressure in adults when other treatments have not worked.

2. What you need to know before you take <Invented name>

Do not take <Invented name>:

- 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
- if you have a slow pulse
- if you have difficulty urinating
- if you have certain forms of cardiovascular disease (ask your doctor if this applies to you)
- if you have elevated pressure in the eye (glaucoma) or poor vision as a result of diabetes
- if you have an overactive thyroid gland
- if you have hormonal disorders caused by a tumour in the adrenal medulla (pheochromocytoma)
- if you have acute kidney disease or severe renal impairment
- if you have an enlarged prostate

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine as well as during treatment:

- if you get high blood pressure when lying down. Symptoms of high blood pressure are e.g. palpitations,

shortness of breath, chest pain, headache and blurred vision. If this applies to you, it is important that your blood pressure is checked regularly when you lie down and when you stand up, as there may be a risk that your blood pressure will rise at night when you are sleeping. Your doctor will then decide if the dose is to be adjusted or if you should stop taking <Invented name>. **It is important that you do not take this medicine late in the evening** (see section "How to take <Invented name>").

- if your blood pressure drops further when standing up: in this case, treatment with this medicine must be discontinued

- if you experience any signs or symptoms that indicate low heart rate (bradycardia) such as slow pulse, dizziness or increased cardiac awareness, consult your doctor as you may be advised to stop taking <Invented name>.

- if you experience problems with the circulation, which may, for example, appear as pain or cramp in the stomach (especially after eating) or in the legs.

- if you have prostate problems, as you may experience difficulty in urinating when taking this medicine. Your kidney and liver function and your blood pressure will be checked by your doctor before you start using this medicine and then regularly during treatment, and if necessary, the dose will be adjusted.

Children and adolescents

Not recommended to children and adolescents under the age 18 because the safety and efficacy of <Invented name>tablets in this age group have not been established.

Other medicines and <Invented name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- Medicinal products that when used in combination with Midodrin Evolan may cause the blood pressure to rise a lot:
 - some medicines used to reduce high blood pressure (e.g reserpine and guanethidine)
 - medicines used to treat allergies (antihistamines)
 - hormones used when the thyroid is not working properly
 - some medicines used to treat depression (tricyclic antidepressants and MAO-inhibitors)
 - medicines that narrow blood vessels (vasoconstrictors)
 - medicines that have a stimulating effect on certain parts of the nervous system (sympathomimetic agents)
- some medicines used to treat heart disease (e.g prazosin and phentolamine) because the effect of <Invented name> is blocked by these drugs.
- digitalis preparations (a type of medicines used to treat heart disease) because concomitant use with <Invented name> may lead to cardiac dysfunction.
- corticosteroids (a type of anti-inflammatory medicine), since the blood pressure enhancing effect of both drugs may be enhanced when taken together
- medicines which reduce your heart rate.

Pregnancy, breast-feeding and fertility

It is not recommended to use this medicine during pregnancy. Tell your doctor if you are, or wish to become pregnant, while you are being treated with this medicine.

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 muddle-headedness occurs after taking this medicine.

3. How to take <Invented name>

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Swallow the tablets with a glass of water. This medicine may be taken with or without food.

How much you should take

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

The recommended starting dose is one tablet of 2.5 mg three times a day. This dose can be increased once weekly up to four 2.5 mg tablets, or two 5 mg tablets three times daily (up to a total of 30 mg per day).

Timing of the evening dose

Avoid taking this medicine in the late evening. The last dose should be taken at least 4 hours before your bedtime to avoid the blood pressure from rising when you lie down. 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 “Warnings and precautions” of this leaflet.

If you feel that the effect of this medicine is too strong, or too weak, talk to your doctor or pharmacist.

Elderly

If you are older, your doctor will increase your dose especially carefully because the information regarding the dosage for the elderly is limited.

If you take more <Invented name> than you should

Taking too much of this medicine can cause:

If you have used too much of this medicine, you may experience increased blood pressure (with symptoms such as palpitations, shortness of breath, chest pain, headache and blurred vision), slow heart rate, difficulty in urinating, getting goosebumps or cold-like symptoms.

If you forget to take <Invented name>

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

If you stop taking <Invented name>

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, <Invented name> can cause side effects, although not everybody gets them.

Stop taking <Invented name> and **contact your doctor immediately** or visit the nearest emergency department if you experience the following symptoms, see also the section "What you need to know before taking <Invented name>"

- heart palpitations, shortness of breath, chest pain, headache and blurred vision when lying down are signs of hypertension, a common side effect that may occur in up to 1 in 10 users.
- slow heart rate is a sign of bradycardia an uncommon side effect which may occur in up to 1 in 100 users.)

Other side effects that may occur:

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

Common (may affect up to 1 in 10 people): tingling and itching, headache, nausea (feeling sick), heartburn, inflammation in the mouth, flushing, rash, cold, difficulty urinating.

Uncommon (may affect up to 1 in 100 people): sleep disturbances including difficulty sleeping, restlessness, agitation and irritability, urge to urinate.

Rare (may affect up to 1 in 1,000 people): palpitations, rapid heartbeat, abnormal liver function including an increase in the number of liver enzymes (shown in blood tests).

Not known (frequency cannot be estimated from the available data): abdominal pain, being sick (vomiting), diarrhoea, anxiety, confusion.

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 national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

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 blister and box. The expiry date refers to the last day of that month.

Store below 25°C.

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 to protect the environment.

6. Contents of the pack and other information

What <Invented name> contains

The active substance is midodrine hydrochloride.

Each tablet contains either 2.5 mg or 5 mg midodrine hydrochloride.

The other ingredients are microcrystalline cellulose, maize starch, magnesium stearate, and silica

colloidal anhydrous.

What <Invented name> looks like and contents of the pack

The 2.5 mg tablets are white, flat, round tablets embossed with “2.5”.

The 5 mg tablets are white, flat, round tablets embossed with “5”.

2.5 mg tablets are available in packs of 10, 20, 30, 40, 50, 60, 70, 80, 90, 100 and 500 tablets

5 mg tablets are available in packs of 10, 20, 30, 40, 50, 60, 70, 80, 90, 100 and 500 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Evolan Pharma AB

Box 120

182 12 Danderyd

Sweden

Manufacturer

Medis International a.s.

výrobní závod Bolatice

Průmyslová 961/16

747 23 Bolatice

Czech Republic

This leaflet was last revised in 2020-03-31.

[To be completed nationally]