PATIENT INFORMATION LEAFLET

MIDODRINE HYDROCHLORIDE 2.5 MG & 5 MG TABLETS

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.

In this leaflet:

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

The name of this medicine is Midodrine Hydrochloride Tablets. The active ingredient is 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 Midodrine Hydrochloride Tablets

Do not take Midodrine Hydrochloride Tablets if:

- You are allergic to midodrine hydrochloride or any of the other ingredients of this medicine (listed in section 6 of this leaflet)
- You have high blood pressure, or a form of low blood pressure known as vasovagal hypotension
- You have severe heart disease including slow pulse, heart attack, heart failure, heart rhythm disorders, widening of the aorta (aortic aneurysm)
- You have difficulty in urinating
- You have certain forms of cardiovascular disease
- You have elevated pressure in the eye (glaucoma) or poor vision as a result of diabetes
- You have an overactive thyroid
- You have hormonal disorders caused by a tumour in the adrenal medulla (pheochromocytoma)
- You have severe kidney disease
- You have an enlarged prostate

If you suffer from any of the above, speak to your doctor or pharmacist before taking Midodrine Hydrochloride Tablets.

Warnings and Precautions
Talk to your doctor or pharmacist before taking this medicine 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 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 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 disorders), 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 circulation.
- Suffer from a disease of the prostate, as you may find passing urine is difficult when taking this medicine.

You should have your kidney 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 Hydrochloride Tablets.

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 effect of Midodrine Hydrochloride Tablets in this age group has not been established.

Other medicines and Midodrine Hydrochloride Tablets
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Taking some medicines together can be harmful.

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

- Reserpine and guanethidine (medicines used to reduce high blood pressure), antihistamines (used to

treat allergies), hormones for the thyroid (used when the thyroid is not working properly), tricyclic antidepressants and MAO-inhibitors (both used to treat depression) and other vasoconstrictors (medicines that narrow blood vessels), or sympathomimetic agents (medicines that have a stimulating effect on certain parts of the nervous system) because concomitant use with this medicine may cause a large increase in blood pressure.
- Prazosin and phentolamine (medicines used to treat heart disease) because the effect of this medicine is blocked by these drugs.
- Digitalis preparations (medicines used to treat heart disease) because concomitant use with this medicine may lead to cardiac dysfunction (heart disorder).
- Fludrocortisone acetate (an anti-inflammatory medicine) because this medicine may increase its effect.
- Midodrine can prevent the excretion of drugs such as perphenazine, amiodarone and metoclopramide, causing unexpected higher levels of these drugs to be present in the body.
- Medicines which directly or indirectly reduce your heart rate - it is advisable that your doctor closely monitors you.

If you are unsure of the types of medicines you are taking, ask your doctor or pharmacist.

Pregnancy and breast-feeding
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.

Using this medicine while pregnant is not recommended. Tell your doctor if you are pregnant, or want to be, 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 light-headedness occurs after taking this medicine. If this happens to you, do not drive or use machinery and ask your doctor for advice.

3. How to take Midodrine Hydrochloride Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with them if you are not sure. Swallow tablets with a drink of water. This medicine may be taken with or without food.

The score-line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

How much should you 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 normally one tablet of 2.5 mg two or three times a day. Your doctor may increase the dose each week until the best effect is seen. The recommended total daily dose should be spread evenly into three doses per day. The maximum daily dose is 30 mg given in divided doses.

You should take the tablets during the daytime, when you are upright, at intervals of 3-4 hours. The last dose should be taken at least four hours before bedtime.

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

If you take more Midodrine Hydrochloride Tablets than you should:
If you accidentally take too many tablets, or someone else takes any of your medicine, you should tell your doctor at once or contact the nearest accident and emergency department. Show any left-over medicines or the empty packet to the doctor.

Signs and symptoms of taking too many tablets can include high blood pressure (hypertension), slow heart rate (bradycardia), difficulty urinating, goosebumps and feelings of coldness.

If you forget to take Midodrine Hydrochloride Tablets:
Do not worry. Take your usual dose at the next correct time. 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 Midodrine Hydrochloride Tablets:
Always talk to your doctor if you are considering stopping this medicine.

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

4. Possible side effects

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

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

Common (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 (feeling sick), heartburn, inflammation of the lining inside the mouth, flushing, rash, chills, difficulty urinating.

Uncommon (may affect more than 1 in 1,000 but less than 1 in 100 people):
- Sleep disturbances including difficulty sleeping, restlessness, agitation and irritability, slowed heart rate, urge to urinate.

Rare (may affect more than 1 in 10,000 but less than 1 in 1,000 people):

- Palpitations, rapid or irregular heartbeat, chest pain, abnormal liver function including an increase in the liver enzymes, dizziness or light headedness, stroke, visual disturbances.

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

- Abdominal pain, being sick (vomiting), diarrhoea, anxiety, feelings of confusion, increased tear production.

Reporting of side effects
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. You can also report side effects directly via HPRA 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 Midodrine Hydrochloride Tablets

Keep this medicine out of the sight and reach of children.

Store below 30 ºC.

Do not use Midodrine Hydrochloride Tablets after the expiry date on the carton and blister as [EXP XX/YYYY]. 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 Hydrochloride Tablets contain:
Each tablet contains either 2.5 mg or 5 mg of midodrine hydrochloride as the active ingredient.

The tablets also contain microcrystalline cellulose, maize starch, colloidal anhydrous silica and magnesium stearate.

What Midodrine Hydrochloride Tablets look like and contents of the pack:

- The 2.5 mg tablets are white to off white, round biconvex tablets, debossed with “MI” above the score line and “2.5” below the score line and plain on the other side. Diameter 6.3 mm and thickness 2.8 – 3.2 mm.
- The 5 mg tablets are white to off white, round biconvex tablets, debossed with “MI” above the score line and “5” below the score line and plain on the other side. Diameter 7.1 mm and thickness 3.9 – 4.5 mm.

Midodrine Hydrochloride Tablets are available in boxes of 100 tablets.

Marketing Authorisation Holder:
Milstein C.V., Patroonsweg, 20e Zeewolde,
Flevoland, 3892 DB, The Netherlands

Manufacturer:
Tiofarma B.V., Benjamin Franklinstraat 5-10,
Oud-Beijerland, 3261 LW, The Netherlands

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