

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Midodrine Hydrochloride Aspire 2.5 and 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 Hydrochloride Aspire 2.5 and 5 mg Tablets are and what are they used for
2. What you need to know before you take Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets
3. How to take Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets
4. Possible side effects
5. How to store Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets
6. Contents of the pack and other information

#### **1. What Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets are and what are they used for**

Midodrine Hydrochloride Aspire 2.5 and 5 mg 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.

Midodrine Hydrochloride Aspire 2.5 and 5 mg 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 Hydrochloride Aspire 2.5 and 5 mg Tablets**

##### **Do not take Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets if you:**

- are allergic to midodrine hydrochloride or any of the other ingredients of this medicine (listed in 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 Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets at least four hours before bedtime. This is because Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets can cause high blood pressure if you are lying down for any period of time (for example, sleeping or sunbathing).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking this medicine 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.

### **Other medicines and Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription.

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

- 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). Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets may increase the effect of this drug
- metoclopramide (used to stop you feeling and being sick). Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets may increase the effect of this drug
- phenothiazines and atypical antipsychotics for schizophrenia or psychosis
- antihistamines for allergies
- appetite suppressants, e.g., benzphetamine, diethylpropion, phendimetrazine, phentermine tend to increase blood pressure and heart rate and may cause excessive hypertension
- nasal/ sinus congestion relievers, especially those purchased without a prescription
- thyroid hormones
- Corticosteroids (for example, fludrocortisone). In combination with Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets, corticosteroids may increase the risk of eye problems or a high blood pressure whilst lying down. (These drugs are sometimes used together with Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets, and your doctor may have prescribed this combination for you).

### **Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets with food**

Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets may be taken with or without food.

### **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 for advice before taking this medicine.

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

Do not take this medicine while breast-feeding.

### **Driving and using machines**

Midodrine Hydrochloride Aspire 2.5 and 5 mg 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.

### **Midodrine Hydrochloride Aspire 5 mg Tablets contain sunset yellow FCF (E110)**

Sunset yellow can cause allergic reactions.

## **3. How to take Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets**

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 tablet whole with a drink of water
- You should take your last dose of Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets at least four hours before bedtime. This is because Midodrine Hydrochloride Aspire 2.5 and 5 mg 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 2.5mg (1 tablet of 2.5mg) taken 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 30mg a day taken as 3 divided doses. 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 Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets.
- If you have liver problems, you should consult your doctor. The safety of Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets in patients with liver problems has not been established.

### **If you take more Midodrine Hydrochloride Aspire 2.5 and 5 mg 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 Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets**

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 Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets**

Do not stop taking these tablets without asking your doctor first (except if you experience signs of an allergic reaction, if this occurs stop taking the medicine and seek medical help immediately.)

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. STOP taking Midodrine Hydrochloride Aspire 2.5 and 5 mg 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.
- you experience any chest pain, palpitations, shortness of breath, headache, blurred vision, pulse slowing, increased dizziness or faintness.

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.

Midodrine Hydrochloride Aspire 2.5 and 5 mg 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 Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets, or recommend that you raise the head of your bed.

If you are using Midodrine Hydrochloride Aspire 2.5 and 5 mg 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 or pharmacist. 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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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 Aspire 2.5 and 5 mg Tablets**

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 carton or blister. The expiry date refers to the last day of that month.

Do not store above 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 protect the environment.

## **6. Contents of the pack and other information**

**What Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets contains**

The active substance is midodrine hydrochloride and each tablet contains either 2.5 mg or 5 mg midodrine hydrochloride.

The other ingredients are cellulose microcrystalline, maize starch, magnesium stearate, talc and silica colloidal anhydrous.

Midodrine Hydrochloride Aspire 5 mg Tablets also contain Sunset Yellow FCF (E110).

**What Midodrine Hydrochloride Aspire 2.5 and 5 mg Tablets look like and contents of the pack**

The Midodrine Hydrochloride Aspire 2.5 mg Tablets are white, round tablets with M2 debossed on one side and score line on the other side.

The Midodrine Hydrochloride Aspire 5 mg Tablets are orange, round tablets with M5 debossed on one side and 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, 112 or 120 tablets.

Not all packs may be marketed.

**Marketing Authorisation Holder**

Aspire Pharma (Malta) Limited  
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Central Business District  
Birkirkara CBD2010  
Malta

**Manufacturer**

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Tec Labs - Centro de Inovação da FCUL  
Campo Grande, 1749-019 Lisboa  
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Pharmadox Healthcare Limited  
KW20A Kordin Industrial Park,  
Paola PLA 3000, Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark – Augermid  
Norway - Augermid  
Sweden - Augermid 2.5 mg and 5 mg Tablets

**This leaflet was last revised in September 2024.**