PACKAGE LEAFLET: INFORMATION FOR THE USER

Midotense 2.5mg 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 Midotense Tablets are and what they are used for
2. Before you take Midotense Tablets
3. How to take Midotense Tablets
4. Possible side effects
5. How to store Midotense Tablets
6. Contents of the pack and other information

1. WHAT MIDOTENSE TABLETS ARE AND WHAT THEY ARE USED FOR

Midotense Tablets contain the active ingredient midodrine hydrochloride which belongs to a group of medicines called adrenergic and dopaminergic agents. It works by raising your blood pressure and is used to treat certain severe forms of low blood pressure in adults when other treatments have not worked.

2. BEFORE YOU TAKE MIDOTENSE TABLETS

Do NOT take Midotense Tablets if:

- you are allergic to midodrine hydrochloride or any of the other ingredients of Midotense (see section 6 for details)
- you have high blood pressure
- you have certain forms of heart disease (such as angina) or have suffered a heart attack
- you have a slow pulse
- you have difficulty urinating
- you have increased pressure in the eye (glaucoma)
- you have poor vision as a result of diabetes
- you have an over-active thyroid gland
- you have tumour near the kidney causing hormonal disorders (also known as pheochromocytoma)
- you have severe or acute kidney disease or problems
- you have an enlarged prostate

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you have the condition of high blood pressure when you lie down. If you suffer from high blood pressure when you lie down then:

- Regular monitoring of your blood pressure when you are lying down and when you are standing up will be required. This is required to see if you are at 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 of Midotense 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. You should take your last daily dose at least 4 hours before bedtime. This is because Midotense can cause high blood pressure if you are lying down for any period of time. 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 which regulate the function of body organs such as heart and stomach), 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.
- have or had heart disease, either where your heart cannot pump the blood around your body as well as it should (a condition called heart failure) or irregular heart rate, or if you had any blocked or leaking blood vessels including those of heart or brain.
- suffer from problems with your circulation, especially if you have symptoms such as pain or cramps in the stomach after eating, or pain or cramps in the legs after walking.
- are taking medication which reduces heart rate such as digitalis preparations. Taking midodrine may further reduce your heart rate and your doctor may want to monitor your heart rate more closely if you take these medications together.
- 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 regularly, and if necessary your dose adjusted.

It is important that you immediately report symptoms related to high blood pressure, such as chest pain, palpitations, shortness of breath, headache and blurred vision. Your doctor will then decide whether to adjust dosage or stop your treatment with Midotense.

If any of the warnings apply to you, or have had them in the past, talk to your doctor.

Children and adolescents

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

Other medicines and Midotense 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:

- 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), nasal/sinus congestion relievers (vasoconstriction 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 reduced heart rate.
- Steroids (for example, fludrocortisone acetate, an anti-inflammatory medicine) because this medicine may increase its effect
- Medicine(s) which directly or indirectly reduce your heart rate because if this medicine is combined with Midotense it may further reduce your heart rate. It is advisable that your doctor closely monitors you.

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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 before taking Midotense.

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

Driving and using machines
This medicine should not affect your ability to drive or use machines. However, if you feel dizzy or light headed, do not drive or use any tools or machines and ask your doctor for advice.

3. HOW TO TAKE MIDOTENSE TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. 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 normally one tablet of 2.5 mg three times a day. Your doctor may increase this dose weekly up to four 2.5mg tablets (10mg) three times daily. Most people do not need more than 30mg a day. The recommended total daily dose should be spread evenly into three doses per day in divided doses.

Timing of the evening dose
Avoid taking this medicine in the late evening. You should take the last dose at least 4 hours before your bedtime. Raising the position of 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.

If you take more Midotense Tablets than you should
If you have taken more tablets than you should

- Contact your doctor or pharmacist immediately or go to the nearest hospital casualty department straight away.
- Take this leaflet and/or the pack with you so that this medicine can be identified.
- The following effects may happen: high blood pressure (hypertension) e.g. palpitations, shortness of breath, chest pain, headache and blurred vision, low heart rate (bradycardia), urgent desire to empty the bladder, difficulty urinating, hair standing up (goosebumps) or feelings of coldness.

If you forget to take Midotense Tablets
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 Midotense Tablets
There will be no sudden drop in your blood pressure. Do not stop taking these tablets without asking your doctor first. 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, Midotense 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):

- increased blood pressure when lying down, headache, nausea (feeling sick), tingling and itching, flushing, rash, chills, heartburn, inflammation of the lining inside the mouth, 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 heartbeat, abnormal liver function including an increase in the number of liver enzymes.

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

- abdominal pain, being sick (vomiting), diarrhoea, anxiety, feelings of confusion.

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 the Yellow Card Scheme,
website: 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 MIDOTENSE TABLETS

Keep this and all medicine in a safe place out of the sight and reach of children.
Do not take your tablets after the expiry date which is stated on the carton and blister label. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions. Store in the original package to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicines no longer required. This will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Midotense Tablets contain:

- Each tablet contains 2.5mg of midodrine hydrochloride.
- The other ingredients are microcrystalline cellulose, pregelatinised starch, magnesium stearate, silica colloidal anhydrous and talc.

What Midotense Tablets look like and contents of the pack
Midotense are white to off white, 7mm round tablets with a scoreline on one side. The scoreline is only to facilitate swallowing and not to divide into equal doses.

They are supplied in blister packs of 30, 50, 90 or 100 tablets.
Not all sizes may be marketed.

Marketing Authorisation Holder
Transdermal Limited,
Merlin House, Brunel Rd,
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TransDermal

Manufacturer
Specifar S.A, 1, 28 Octovriou str., Ag. Varvara, 123 51 Athens, Greece

For any further information about this medicine, please contact the Marketing Authorisation Holder.

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