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PHARMACODE

Amlodipine 2.5mg, 5mg and 10mg Tablets

amlodipine

Read all of this leaflet carefully before you start taking this medicine because it contains important

- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Amlodipine 2.5mg, 5mg and 10mg Tablets are also referred as Amlodipine tablets in this leaflet.

What is in this leaflet:

- 1. What Amlodipine tablets are and what they are used for
- 2. What you need to know before you take Amlodipine tablets
- 3. How to take Amlodipine tablets
- 4. Possible side effects
- 5. How to store Amlodipine tablets
- 6. Contents of the pack and other information

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

Amlodipine tablets contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists.

Amlodipine tablets is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

In patients with high blood pressure this medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina Amlodipine tablets works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. This medicine does not provide immediate relief of chest pain from

2. What you need to know before you take Amlodipine tablets

Do not take Amlodipine tablets:

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- If you are allergic (hypersensitive) to amlodipine, or any of the other ingredients of this medicine listed in section 6, or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in
- If you have severe low blood pressure (hypotension).
- If you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you suffer from heart failure after a heart attack.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Amlodipine tablets.

You should inform your doctor if you have or have had any of the following conditions:

- Recent heart attack
- Heart failure
- Severe increase in blood pressure (Hypertensive crisis)
- Liver disease
- You are elderly and your dose needs to be increased

Children and adolescents

Amlodipine tablets has not been studied in children under the age of 6 years. This medicine should only be used for hypertension in children and adolescents from 6 years to 17 years of age (see section 3). For more information, talk to your doctor.

Other medicines and Amlodipine tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Amlodipine tablets may affect or be affected by other medicines, such as:

- ketoconazole, itraconazole (anti-fungal medicines) ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- hypericum perforatum (St. John's Wort) verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus, sirolimus, temsirolimus, and everolimus (medicines used to alter the

way your immune system works)

simvastatin (cholesterol lowering medicine) cyclosporine (an immunosuppressant)

Amlodipine tablets may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

Amlodipine tablets with food and drink

Grapefruit juice and grapefruit should not be consumed by people who are taking this tablets. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Amlodipine tablets.

Pregnancy, breast-feeding

Pregnancy

The safety of amlodipine in human pregnancy has not been established. If you think you might be pregnant, or are planning to get pregnant, you must tell your doctor before you take this tablet.

Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts. If you are breast-feeding or about to start breast-feeding you must tell your doctor before taking this tablet.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Amlodipine tablets may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Amlodipine tablets contains sodium This medicine contains less than 1 mmol sodium

(23 mg) per tablet, which means it is essentially

3. How to take Amlodipine 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.

The recommended initial dose is 5 mg once daily. The dose can be increased 10 mg once daily. This medicine can be used before or after food and drinks. You should take this medicine at the

each day with a drink of water. Do not take Amlodipine tablets with grapefruit juice.

Use in children and adolescents

For children and adolescents (6-17 years old), the recommended usual starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day.

It is important to keep taking the tablets. Do not wait until your tablets are finished before seeing your

If you take more Amlodipine Tablets than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Seek immediate medical attention if you take too many tablets.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If you forget to take Amlodipine Tablets

Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amlodipine tablets

Your doctor will advise you how long to take this medicine. Your condition may return if you stop using this medicine before you are advised.

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. Visit your doctor immediately if you experience any of the following side effects after taking this medicine. • Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing

- Swelling of eyelids, face or lips
- Swelling of the tongue and throat which causes great difficulty breathing
- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions
- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling

The following very **common side effect** has been reported. If this causes you problems or if it lasts for more than one week, you should contact your doctor.

Very common: may affect more than 1 in 10 people Oedema (fluid retention)

The following common side effects have been reported. If any of these cause you problems or if they last for more than one week, you should contact your

Common: may affect up to 1 in 10 people • Headache, dizziness, sleepiness (especially at the

- beginning of treatment)
- Palpitations (awareness of your heart beat), flushing
- · Altered bowel habits, diarrhoea, constipation,

- Muscle cramps
- Ankle swelling

Other side effects that have been reported include the following list. If any of these get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Uncommon: may affect up to 1 in 100 people

- · Trembling, taste abnormalities, fainting
- Numbness or tingling sensation in your limbs, loss
- of pain sensation
- Low blood pressure · Sneezing/running nose caused by inflammation of
- the lining of the nose (rhinitis)
- Dry mouth, vomiting (being sick)
- on skin, skin discolouration
- at night, increased number of
- · Inability to obtain an erection, discomfort or
- enlargement of the breasts in men
- Pain, feeling unwell
- Weight increase or decrease
- Rare: may affect up to 1 in 1,000 people Confusion

Very rare: may affect up to 1 in 10,000 people

- · Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding
- Excess sugar in blood (hyperglycaemia) A disorder of the nerves which can cause muscular

- weakness, tingling or numbness
- Swelling of the gums, bleeding gums • Inflammation of the stomach (gastritis) which may be
- associated with abdominal bloating
- Abnormal liver function, inflammation of the liver
- (hepatitis), yellowing of the skin
- (Jaundice), liver enzyme increase which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of blood vessels, often with skin rash Sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

Not known: frequency cannot be estimated from the available data

Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk

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 Yellow Card Scheme at: 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 Amlodipine tablets

Keep this medicine out of the sight and reach of

Do not use this medicine after the expiry date which is stated on the pack after 'EXP'. 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 Amlodipine Tablets contains

The active substance in Amlodipine 2.5mg tablets is amlodipine (as besilate).

The active substance in Amlodipine 5mg tablets is amlodipine (as besilate).

The active substance in Amlodipine 10mg tablets is amlodipine (as besilate). The other ingredients are Microcrystalline cellulose

(PH102), Dibasic Calcium Phosphate (Dihydrate),

Sodium Starch Glycolate (Type-A), Colloidal Anhydrous Silica, Magnesium Stearate. What Amlodipine Tablets looks like and contents

of the pack **2.5mg tablets:** White to off-white, round flat bevelled tablets, debossed with "2.5" on one side and "A" on other side.

5mg Tables: White to off-white, round, flat bevelled tablets, debossed with "A5" on one side and plain on

10mg Tablets: White to off-white, round, flat bevelled tablets, debossed with "A10" on one side and plain on other side. Amlodipine tablets are available in cartons containing

Alu- Alu or Aluminium- PVC/PVDC White Opaque blister packs of 4, 10, 14, 20, 28, 30, 50, 60, 98, 100, 300 or 500 tablets with leaflets inside.

Not all pack sizes may be marketed.

Marketing Authorization Holder

- Flamingo Pharma (UK) Ltd. 1st Floor, Kirkland House,
- 11-15 Peterborough Road,

Harrow, Middlesex, HA1 2AX, United Kingdom.

Manufacturer Flamingo Pharma (UK) Limited

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 Abdominal pain, feeling sick (nausea) indigestion Tiredness, weakness · Visual disturbances, double vision

- Mood changes, anxiety, depression, sleeplessness
- Ringing in the ears
- · Hair loss, increased sweating, itchy skin, red patches
- Disorder in passing urine, increased need to urinate times of passing urine
- Joint or muscle pain, back pain