APPROVED PATIENT INFORMATION LEAFLET FOR AMLODAC 5 / 10 TABLETS

SCHEDULING STATUS

Schedule 3

PROPRIETARY NAME AND DOSAGE FORM

AMLODAC 5 tablets

AMLODAC 10 tablets

Read all of this leaflet carefully before you start taking AMLODAC:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **AMLODAC** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT AMLODAC CONTAINS

Active ingredients:

Each tablet contains amlodipine besylate equivalent to 5 mg or 10 mg amlodipine.

Inactive ingredients:

Colloidal silicon dioxide, dibasic calcium phosphate, iron oxide, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate, starch and talc.

AMLODAC 5 also contains wincoat wt aq-1255 brown (colourant).

AMLODAC 10 also contains hydroxypropyl methyl cellulose and titanium dioxide.

Sugar free.

2. WHAT AMLODAC IS USED FOR

AMLODAC is a medicine that is called a calcium antagonists. **AMLODAC** works by relaxing the blood vessels, so that the blood passes through the blood vessels more easily.

AMLODAC has been prescribed for you in order to treat high blood pressure (hypertension) or a type of chest pain called angina pectoris. **AMLODAC** can be prescribed alone or in combination with other medicines.

3. BEFORE YOU TAKE AMLODAC

Do not take AMLODAC if:

- You are allergic to amlodipine, other calcium antagonists or any of the other ingredients of **AMLODAC** (See **WHAT AMLODAC CONTAINS**).
- You suffer from low blood pressure, cardiogenic shock, aortic stenosis (narrowing of the aortic heart valve) or unstable angina.
- You recently suffered a heart attack (within the past 28 days).

Take special care with AMLODAC:

- Your doctor will not prescribe **AMLODAC** for you if you were diagnosed as having a hypertensive crisis.
- You suffer from kidney problems.
- You have porphyria.
- You suffer from liver problems.
- **IMPORTANT: AMLODAC** are not recommended for children below the age of 18 years.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **AMLODAC**.

Consult your doctor immediately if you become pregnant while taking this **AMLODAC**.

Driving and using machines:

If you suffer from dizziness, headaches, tiredness or nausea, make sure that you are well enough to drive or operate machinery, as your ability to react may be impaired.

Taking other medicines with AMLODAC:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

If you take other medicines for hypertension or angina such as nitroglycerin tablets under the tongue, long acting nitrates or beta-blockers with **AMLODAC [**~~tablets~~**]**, your blood pressure may decrease too much and you may feel very tired and weak.

4. HOW TO TAKE AMLODAC

Do not share medicine prescribed for you with any other person.

Always take AMLODAC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Follow your doctor's advice. The wording on the label will tell you how many tablets to take and when. The tablets should be swallowed whole with a glass of water and should be taken the same time each day.

Your doctor will tell you how long your treatment with **AMLODAC** will last.

Do not stop taking your medicine without consulting your doctor first.

If you have the impression that the effect of **AMLODAC** is too strong or too weak, tell your doctor or pharmacist.

In patients suffering from hypertension, **AMLODAC** may be used either on their own or in combination with other medicines for hypertension.

The usual starting dose is 5 mg once a day. If no improvement is seen after 10 -14 days, your doctor may increase the dose to the maximum of 10 mg per day (taken as a single dose).

If you suffer from liver problems or are an elderly person, your doctor will decide the most suitable dose for you.

If you take more AMLODAC than you should:

In the event of an overdosage, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre immediately. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you missed a dose of AMLODAC:

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed doe and continue to take the next tablet at the usual time. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

AMLODAC can have side effects.

Not all side effects reported for **AMLODAC** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **AMLODAC**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **AMLODAC** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **AMLODAC**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent:

- Shortness of breath.

- Palpitations (a quicker or irregular heart beat).

Less frequent:

- Irregular or slow heartbeat.
- Heart attack (myocardial infarction).
- Chest pain.
- Increased need to urinate.
- Abnormal liver function.
- Inflammation of the liver.
- Jaundice (yellowing of the skin and/or eyes).
- Inflamed pancreas.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Abdominal pain.
- Headache.
- Dizziness.
- Feeling tired, weakness
- Flushing.
- Feeling sick.
- Indigestion.

Less frequent:

- Coughing.
- Constipation, being sick, diarrhoea, gastritis (inflammation of the stomach lining).
- Dry mouth, increased sweating.
- Swelling or soreness of the gums.
- Inability to sleep.
- Irritability.
- Depression.

- Pins and needles, loss of pain sensation.
- Lack of energy.
- Shaking or trembling.
- Visual disturbances.
- Low blood pressure.
- Inflammation of the blood vessels.
- Red patches or other skin colour changes.
- Hair loss (temporary).
- Back pain, muscle or joint pain.
- Enlargement of the male breasts.
- Weight increase or decrease.
- Inability to obtain erection.
- Confusion, mood changes, anxiety.
- Excess sugar in blood.
- Red blood cell damage (unusual bruising and bleeding).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF AMLODAC

- Store at or below 25 °C.
- Store in a cool dry place.
- Protect from light.
- Do not remove blisters strips from outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN**
- Do not use **AMLODAC** after the expiry date printed on the blister strip or carton.
- Return the expired medicine to your pharmacist for safe disposal.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF AMLODAC

AMLODAC 5: PVC / Aluminium foil blister strips containing 10 tablets. 3 or 10 blister strips are packed in an outer carton.

AMLODAC 10: PVC / Aluminium foil blister strips containing 10 tablets. 3 or 10 blister strips are packed in an outer carton.

8. IDENTIFICATION OF AMLODAC

AMLODAC 5 is a brown, round, biconvex, film coated tablet, with a breakline on one side, and plain on other side.

AMLODAC 10 is a white, round, biconvex, film coated tablet, with a breakline on one side, and plain on other side.

REGISTRATION NUMBERS

AMLODAC 5: A39/7.1/0532

AMLODAC 10: A39/7.1/0533

NAME AND ADDRESS OF REGISTRATION HOLDER

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