Approved Patient Information Leaflet for Medicines for Human Use:

Austell-Amlodipine 5 mg

Austell-Amlodipine 10 mg

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine 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.

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

AUSTELL-AMLODIPINE 5 mg TABLETS

AUSTELL-AMLODIPINE 10 mg TABLETS

WHAT AUSTELL-AMLODIPINE CONTAINS

Austell-Amlodipine 5 mg: Each tablet contains amlodipine besilate equivalent to 5 mg amlodipine.

Austell-Amlodipine 10 mg: Each tablet contains amlodipine besilate equivalent to 10 mg amlodipine.

The other ingredients are: Microcrystalline cellulose, calcium hydrogen

phosphate, colloidal silicon dioxide, sodium starch glycolate and magnesium stearate.

WHAT AUSTELL-AMLODIPINE IS USED FOR

Austell-Amlodipine tablets are indicated in the treatment of:

- Mild to moderate hypertension (high blood pressure)
- Angina pectoris (a chest pain, which spreads to the arm, particularly the left, accompanied by a suffocating feeling).

BEFORE YOU TAKE AUSTELL-AMLODIPINE

Do not take AUSTELL- AMLODIPINE Tablets:

- If you are sensitive to dihydropyridine, amlodipine or any of the ingredients in this tablet.
- If you suffer from myocardial shock, acute unstable angina or aortic stenosis (a narrow aorta).
- If you experience ischaemic pain following administration of Amlodipine (a decrease in blood supply to the heart muscle due to narrow arteries).
- If you suffer from heart failure or severe peripheral arterial disease.

Pregnancy & Breastfeeding:

If you are pregnant or breastfeeding your baby while taking this medicine, please contact your doctor, pharmacist or other health care professional for advice.

Take special care with AUSTELL-AMLODIPINE if you are using:

Other antihypertensive drugs such as beta–blockers;

- Antipsychotics,
- Antidiabetics
- Drugs such as quinidine, carbamazepine, phenytoin
- Cimetidine and erythromycin

Interactions:

"If you are taking other medicines, including complementary or traditional medicines on a regular basis, the use of this medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice"

HOW TO TAKE AUSTELL-AMLODIPINE

Adults

For the management of both high blood pressure and angina the usual initial dose is 5 mg once daily, increased, if necessary, to 10 mg once daily. Take this with one glass of water.

Take the tablets every day at the same time each day. This will have the best effect. It will also help you remember when to take the tablets.

Children

Safety of AUSTELL-AMLODIPINE tablets in children has not been established.

If you forget to take AUSTELL-AMLODIPINE:

Contact your doctor or pharmacist. Do not take a double dose to make up for the forgotten individual doses.

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

Do not take medicines prescribed for you with others.

"In the event of over-dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre".

POSSIBLE SIDE EFFECTS

"Not all side-effects reported for this medicine are included in this leaflet. If your general state of health worsens while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice".

Like all medicines, **AUSTELL-AMLODIPINE** tablets can have side effects.

If any of the following happen, stop taking Amlodipine tablets and tell your doctor immediately or go to the casualty department at your

nearest hospital:

Central Nervous System

More Common:

Dizziness, flushing, headache, palpitations, lethargy.

Less Common:

Mental depression, tremor, flushes.

Gastro-intestinal problems

More Common:

Nausea (feeling sick), vomiting.

Less Common:

Stomach pain, altered bowel habits.

Cerebro-vascular

More Frequent:

Peripheral oedema (swelling of the extremities).

Less Frequent:

Decrease in blood pressure may lead to cerebral ischaemia, heart attack or temporary blindness, vasculitis (17.1 / 18)

Cardiac

Less Frequent:

Increase heart beat, increase in chest pains at start of treatment, irregular heart beats. (18)

Allergic reactions

Less frequent:

Rashes, erythema multiforme, itch, angioedema (18)

Liver

Less frequent:

Abnormalities in liver function, including cholestasis, hepatitis (infection of the liver), which can be severe to require hospitalization.

Other

Less frequent:

Eye pain, fever, swelling of the gums, muscle pain, sexual dysfunction, hair loss, muscle pain and cramps, asthenia, back pain, thirst, dry mouth, shortness of breath, swelling of the breasts, increased blood sugar, increase urination, leucopenia, thrombocytopenia, mood changes, peripheral neuropathy and increased sweating (18).

STORING AND DISPOSING OF AUSTELL-AMLODIPINE

Keep this medicine in a cool dry place at or below 25 °C. Protect from light.

Keep blisters in the carton until required for use.

DO NOT USE AFTER THE DATE, WHICH IS STAMPED ON THE

PACK.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not throw unused tablets in drains or toilets.

PRESENTATION OF AUSTELL-AMLODIPINE

AUSTELL–AMLODIPINE 5 mg:

Blister pack of 28’s, 30’s, 56’s or 84’s tablets.

AUSTELL–AMLODIPINE 10 mg:

Blister pack of 28’s, 30’s, 56’s or 84’s tablets.

IDENTIFICATION OF AUSTELL-AMLODIPINE

AUSTELL–AMLODIPINE 5 mg:

White to off- white, round, biconvex, uncoated tablets, with ‘5’ debossing on one side.

AUSTELL–AMLODIPINE 10 mg:

White to off- white, round, biconvex, uncoated tablets, with ‘10’ debossing on one side.

REGISTRATION NUMBER OF AUSTELL-AMLODIPINE

AUSTELL-AMLODIPINE 5 mg: A39/7.1/0545

AUSTELL-AMLODIPINE 10 mg: A39/7.1/0546

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