

**PROPOSED PATIENT INFORMATION LEAFLET FOR PHARMA DYNAMICS
AMLODIPINE BESYLATE**

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

PHARMA DYNAMICS AMLODIPINE BESYLATE 5 mg (tablets).

PHARMA DYNAMICS AMLODIPINE BESYLATE 10 mg (tablets).

Read this entire leaflet carefully before you start taking PHARMA DYNAMICS

AMLODIPINE BESYLATE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **PHARMA DYNAMICS AMLODIPINE BESYLATE** 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 PHARMA DYNAMICS AMLODIPINE BESYLATE CONTAINS:

Active ingredients:

The active ingredient in **PHARMA DYNAMICS AMLODIPINE BESYLATE** is amlodipine.

Each **PHARMA DYNAMICS AMLODIPINE BESYLATE 5 mg** contains amlodipine besylate equivalent to 5 mg amlodipine

Each **PHARMA DYNAMICS AMLODIPINE BESYLATE 10 mg** contains amlodipine besylate equivalent to 10 mg amlodipine.

Inactive ingredients:

Colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, pregelatinised starch,

PROPOSED PATIENT INFORMATION LEAFLET FOR PHARMA DYNAMICS

AMLODIPINE BESYLATE

sodium starch glycolate.

PHARMA DYNAMICS AMLODIPINE BESYLATE tablets are sugar-free.

2. WHAT PHARMA DYNAMICS AMLODIPINE BESYLATE IS USED FOR:

PHARMA DYNAMICS AMLODIPINE BESYLATE belongs to a group of medicines called calcium channel blocking medicines (dihydropyridine calcium antagonists).

PHARMA DYNAMICS AMLODIPINE BESYLATE may be used alone or in combination with other medicines used to treat high blood pressure and angina.

3. BEFORE YOU TAKE PHARMA DYNAMICS AMLODIPINE BESYLATE:

Do not take **PHARMA DYNAMICS AMLODIPINE BESYLATE**:

- If you are hypersensitive (allergic) to amlodipine, dihydropyridine (used to lower blood pressure) or any of the other ingredients of **PHARMA DYNAMICS AMLODIPINE BESYLATE** (see **WHAT PHARMA DYNAMICS AMLODIPINE BESYLATE CONTAINS**).
- If you suffer from severe hypotension (severe low blood pressure, symptoms include light headedness or dizziness).
- If you have previously experienced shock which could include cardiogenic shock (this is the term used when blood pressure becomes so low that your heart stops working properly and medical treatment is required).
- If you recently (within the past 28 days) suffered a heart attack.
- If the blood flow from the left side of your heart is obstructed (e.g. aortic valve narrowing).
- If you have unstable angina (chest pain which may occur when you are resting).
- If you are pregnant or breastfeeding your baby (see **PREGNANCY AND LACTATION**).
- If you are younger than 18 years of age.

PROPOSED PATIENT INFORMATION LEAFLET FOR PHARMA DYNAMICS AMLODIPINE BESYLATE

Take special care with PHARMA DYNAMICS AMLODIPINE BESYLATE:

- If your doctor diagnosed you with severe high blood pressure.
- If you suffer from aortic stenosis with symptoms such as fatigue, feeling faint or fainting when exercising and shortness of breath.
- If you need to undergo blood tests as the use of **PHARMA DYNAMICS AMLODIPINE BESYLATE** may interfere with the results.
- If you have low blood pressure or other heart conditions.
- If you suffer from liver problems.
- If you suffer from severe kidney problems.
- If you are younger than 18 years of age.
- If you experience chest pain when taking **PHARMA DYNAMICS AMLODIPINE BESYLATE**.
- If you suffer from diabetes.
- If you are an elderly patient.
- If you are about to have a procedure where you would need general anaesthesia.

Taking PHARMA DYNAMICS AMLODIPINE BESYLATE with food and drink:

PHARMA DYNAMICS AMLODIPINE BESYLATE can be taken with or without food.

Pregnancy and Breastfeeding:

Do not take **PHARMA DYNAMICS AMLODIPINE BESYLATE** if you are pregnant, suspect that you are pregnant or breastfeeding your baby and please consult your doctor or pharmacist or other healthcare professional for advice before using **PHARMA DYNAMICS AMLODIPINE BESYLATE**.

If you are pregnant, or become pregnant whilst taking **PHARMA DYNAMICS AMLODIPINE**

PROPOSED PATIENT INFORMATION LEAFLET FOR PHARMA DYNAMICS

AMLODIPINE BESYLATE

BESYLATE, stop taking **PHARMA DYNAMICS AMLODIPINE BESYLATE** and talk to your doctor as soon as possible.

Driving and using machines:

PHARMA DYNAMICS AMLODIPINE BESYLATE can cause dizziness. Do not drive or operate heavy machines until you know how **PHARMA DYNAMICS AMLODIPINE BESYLATE** will affect you.

Taking other medicines with **PHARMA DYNAMICS AMLODIPINE BESYLATE**:

Always tell your healthcare professional if you are taking other medicines.

(This includes complementary or traditional medicines).

Medicine that may influence **PHARMA DYNAMICS AMLODIPINE BESYLATE**:

- Other medicines for hypertension (high blood pressure) or angina (chest pains) such as nitro-glycerine tablets under the tongue, long acting nitrates, beta-blockers or calcium channel blockers (such as verapamil, diltiazem), as this may increase the levels of **PHARMA DYNAMICS AMLODIPINE BESYLATE** in the blood.
- Aldesleukin used in the treatment of kidney cancer and skin melanoma or medicines used to treat mental conditions (antipsychotics), as this may increase the levels of **PHARMA DYNAMICS AMLODIPINE BESYLATE** in the blood.
- Medicines used to treat diabetes as the doses of these medicines may need to be adjusted.
- Medicines that alter the heart rate (such as quinidine or procainamide).
- Certain medicines used to treat fits (carbamazepine, phenobarbital, phenytoin), as these may reduce the effect of **PHARMA DYNAMICS AMLODIPINE BESYLATE**.
- Sodium valproate (used for epilepsy) as this may increase **PHARMA DYNAMICS AMLODIPINE BESYLATE** blood levels. (Discuss with your doctor if you are unsure).

PROPOSED PATIENT INFORMATION LEAFLET FOR PHARMA DYNAMICS

AMLODIPINE BESYLATE

- Medicines used to treat viral, fungal and bacterial infections (such as clarithromycin, erythromycin, ketoconazole, itraconazole or rifampicin) as these may lead to either increased or decreased levels of **PHARMA DYNAMICS AMLODIPINE BESYLATE** in the blood.
- Ritonavir used in the treatment of HIV infections as this may lead to increased levels of **PHARMA DYNAMICS AMLODIPINE BESYLATE** in the blood.
- Dantrolene (a muscle relaxant) may affect potassium levels in the blood.
- Lithium, as this may result in toxic blood concentrations if used in combination with **PHARMA DYNAMICS AMLODIPINE BESYLATE**.
- Simvastatin (used to lower cholesterol), as this may result in increased levels of simvastatin in the blood. The simvastatin dose may need to be reduced.

Tell your doctor before you receive anaesthesia that you are taking **PHARMA DYNAMICS AMLODIPINE BESYLATE**.

4. HOW TO TAKE PHARMA DYNAMICS AMLODIPINE BESYLATE:

Do not share medicines prescribed for you with any other person. Always take **PHARMA DYNAMICS AMLODIPINE BESYLATE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Adults:

A normal starting dose of 5 mg **PHARMA DYNAMICS AMLODIPINE BESYLATE** once a day, taken at the same time every day with or without food.

The tablets should be swallowed whole, with a glass of water.

If no improvement is seen after 10-14 days, your doctor may increase the dose to the maximum of 10 mg **PHARMA DYNAMICS AMLODIPINE BESYLATE** per day (taken as a single dose).

PROPOSED PATIENT INFORMATION LEAFLET FOR PHARMA DYNAMICS AMLODIPINE BESYLATE

Your doctor will decide on the dose depending on your condition.

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

If you take more PHARMA DYNAMICS AMLODIPINE BESYLATE than you should:

In the event of an overdose, with symptoms such as severe dizziness and fainting, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre immediately.

If you forget to take a dose of PHARMA DYNAMICS AMLODIPINE BESYLATE:

If you forget to take a dose of **PHARMA DYNAMICS AMLODIPINE BESYLATE**, take the dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet or tablets at the usual time. Do not take a double dose to make up for the forgotten individual doses.

Effects when treatment with PHARMA DYNAMICS AMLODIPINE BESYLATE is stopped:

It is important that you continue the course of treatment even if you begin to feel better after a few days. If your treatment with **PHARMA DYNAMICS AMLODIPINE BESYLATE** is stopped suddenly, your chest pain may worsen.

5. POSSIBLE SIDE EFFECTS:

PHARMA DYNAMICS AMLODIPINE BESYLATE may have side effects. Not all side effects reported for **PHARMA DYNAMICS AMLODIPINE BESYLATE** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **PHARMA DYNAMICS AMLODIPINE BESYLATE** please consult your doctor, pharmacist or other

PROPOSED PATIENT INFORMATION LEAFLET FOR PHARMA DYNAMICS

AMLODIPINE BESYLATE

healthcare professional for advice.

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

- Swelling of the hands, feet ankles, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Jaundice (yellow discolouration of the skin and eyes).

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

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

- Slow heartbeat (bradycardia) or rapid heartbeat (tachycardia), palpitations.
- Low blood pressure (hypotension) with symptoms such as fainting or light-headedness.
- High blood sugar levels (hyperglycaemia).
- Hepatitis, a liver condition, with symptoms such as stomach pain, fever, nausea, vomiting or loss of appetite.
- Weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis).
- Fainting (syncope).
- Kidney problems (passing less urine than is normal for you).
- Pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever).

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

PROPOSED PATIENT INFORMATION LEAFLET FOR PHARMA DYNAMICS AMLODIPINE BESYLATE

Tell your doctor if you notice any of the following:

- Abnormal blood test results.
- Joint pain, back pain, muscle cramps or weakness.
- Headache, dizziness and fatigue.
- Mood and/or sleep disorders.
- Reduced sense of touch or sensation (numbness).
- Tingling sensation in hands, feet or lips (feeling of “pins and needles”).
- Involuntary trembling (tremors).
- Blurred vision, worsening eyesight.
- Ringing in the ears (tinnitus).
- Flushing.
- Sweating.
- Cough.
- Inflammation of the mucous membrane in the nose (rhinitis).
- Constipation, stomach pain, nausea, vomiting, diarrhoea, indigestion.
- Dry mouth, swelling of the gums.
- High cholesterol.
- Skin conditions such as rash, excessive skin pigmentation, hives, itchy skin.
- Swelling in any part of the body.
- Change taste perception (including loss of taste),
- Problems with sexual performance.

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

PROPOSED PATIENT INFORMATION LEAFLET FOR PHARMA DYNAMICS

AMLODIPINE BESYLATE

6. STORING AND DISPOSING OF PHARMA DYNAMICS AMLODIPINE BESYLATE:

PHARMA DYNAMICS AMLODIPINE BESYLATE should be stored in the original packaging (keep blisters in the carton until required for use) at or below 25 °C

KEEP MEDICINE OUT OF THE REACH OF CHILDREN.

Do not use after the expiry date stated on the label and carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

8. IDENTIFICATION OF PHARMA DYNAMICS AMLODIPINE BESYLATE:

PHARMA DYNAMICS AMLODIPINE BESYLATE 5 mg: A white, round, slightly biconvex, bevelled edge tablet, scored on one side. Diameter: 8,0 mm.

PHARMA DYNAMICS AMLODIPINE BESYLATE 10 mg: White, round (diameter 10,5 mm), slightly biconvex, with bevelled edges.