PACKAGE LEAFLET: Information for the patient

PROAMLO

Tablets – 5 mg

(Amlodipine besilate)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT PROAMLO IS AND WHAT IT IS USED FOR

Proamlo contains amlodipine, which is a calcium-channel blocker of the dihydropyridine group and prevents transmembrane displacement of the calcium ions in cardiac smooth muscles and those of the blood vessels. The antihypertensive action is due to the relaxing effect on the smooth muscles of arteries.

The exact mechanism by which amlodipine relieves angina has not been finally determined but amlodipine reduces the total ischemic burden due to the following actions:

1) amlodipine dilates peripheral arterioles and thus reduces the total peripheral resistance against which the heart works; since the heart speed remains constant, the heart load reduction reduces energy consumption and myocardial oxygen requirements;
2) the mechanism of action of amlodipine also may include enlargement of the main coronary arteries and coronary arterioles, either in normal and also ischemic regions; the enlargement increases myocardial oxygen supply in patients with coronary artery spasm (Prinzmetal angina).

Indications:

- *Hypertension*, it may be used alone or in combination with other antihypertensive agents.
- *Ischemic heart disease* (chronic stable angina), it may be used alone or in combination with other antianginal agents.
- *Vasospastic angina* (Prinzmetal's angina), as monotherapy or with other antianginal drugs.

Your doctor may have given Proamlo for a different purpose. Ask your doctor if you want to know why you were given this medicine.

2. BEFORE YOU TAKE PROAMLO

Do not take Proamlo if:

- you are allergic to amlodipine besilate or to any of the excipients of the tablet;
- you are allergic to iodine;
- you have hypersensitivity from dihydropyridines;
- you have cardiogenic shock;
- you have significant aortic stenosis;
- you suffer from unstable angina;
- you suffer from severe hypotension.

If you think that you suffer from any of the conditions mentioned above, do not take the tablets, go and talk with your doctor first and follow the advice given.

Take special care with Proamlo

Tell your doctor if:

- you are allergic to other medicines, especially if they are in the same class of drugs as Proamlo;
- you plan to get pregnant, or you are pregnant during the time that you are using Proamlo;
- you suffer from heart failure;
- you have impaired liver function, because in these cases the half-life of amlodipine increases; in these cases the dose of Proamlo must be reduced;
- the patient is under 6 years old (in this case Proamlo is not recommended);
- you have experienced a heart attack (myocardial infarction) recently.

You should not stop the drug immediately because deterioration of angina may happen.
Care should be taken in the elderly if an increase of the dose is required.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Proamlo.
Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, even those without a prescription. Do not forget to inform your doctor for the treatment with Proamlo if you are given any other drug during treatment.
In vitro studies in human plasma have shown that amlodipine does not affect the protein binding of digoxin, phenytoin, warfarin or indomethacin.

Proamlo can interact with:

- CYP3A4 inhibitors: concomitant administration of amlodipine with strong or moderate CYP3A4 inhibitors: (*protease inhibitors*: ritonavir, indinavir, nelfinavir; *azole antifungals*: itraconazole, ketoconazole; *macrolides like*: erythromycin, clarithromycin, telithromycin; *verapamil, diltiazem*) can significantly increase the amlodipine exposure;
- CYP3A4 inducers: concomitant use of amlodipine with CYP3A4 inducers (e.g., rifampicin, hypericum perforatum) may give a lower plasma concentration of amlodipine.
- dantrolene;
- simvastatin: amlodipine increases the plasmatic concentration of simvastatin and the risk for

myopathy;

- aminophylline: the plasmatic concentration of aminophylline and its effect increase;
- theophylline: the plasmatic concentration of theophylline increases;
- phenobarbital, primidone: the effect of amlodipine decreases;
- tacrolimus: during concomitant treatment its dose should be reduced, because the toxicity of tacrolimus increases;
- ciclosporin (an immunosuppressor).

Proamlo may lower blood pressure even more if you take also other medicines to treat high blood pressure.

Taking Proamlo with food and drinks

Grapefruit and grapefruit juice must not be taken together with Proamlo because they increase the hypotensive effect of the drug.

It should not be consumed at the same time with alcohol because the hypotensive effect increases.

Pregnancy

Inform your doctor or pharmacist if you are pregnant or are planning a pregnancy.

There are no suitable and well-controlled studies in pregnant women.

Proamlo may be used during pregnancy only when the possible benefits justify the possible risk to the fetus.

The doctor or the pharmacist will discuss about the risk and benefits of taking it during pregnancy.

Breastfeeding

Inform your doctor or pharmacist if you are breastfeeding your baby.

It is not known whether amlodipine is excreted in breast milk, so in the absence of this information, it is recommended that breast-feeding should be interrupted during the administration of Proamlo.

The doctor or pharmacist will discuss about the risk and benefits of taking it if you are

breastfeeding your baby or are planning to do it.

Driving and using machinery

The treatment with Proamlo is unlikely to impair the ability of the patient to drive or use different machinery. However, side effects like dizziness and syncope may have an influence, hence the patients must be informed.

Be careful when driving or using machinery until you see how Proamlo affects you.

3. HOW TO TAKE PROAMLO

Always take Proamlo tablets according to medical advice. If you feel that the effects of Proamlo are too strong or too weak, talk to your doctor or pharmacist.

Below is given a practic overview of the dosage of Proamlo.

Adults: for the treatment of hypertension, the initial dose is 5 mg once daily with a maximum dose of 10 mg once daily. Fragile individuals, elderly, or patients with hepatic failure may start with 2.5 mg once daily and this dose may be used even when other antihypertensives are added to the therapy with Proamlo.

The recommended dose for the treatment of chronic stable or vasospastic angina is 5 - 10 mg; lower doses are suggested in the elderly and in patients with hepatic failure.

Children: the oral antihypertensive dose in children aged 6 - 17 years old is 2.5 - 5 mg once daily**.** Doses higher than 5 mg daily are not studied in children.

Ask your doctor if you are not sure for how long you should continue the treatment with Proamlo.

Proamlo must be swallowed as a whole tablet with a glass of water.

If you take more Proamlo than you should

If you take more Proamlo than you should, or if the children have wrongly taken this drug, please contact your doctor, hospital, or call the emergency to get an opinion on the risk and advice on the actions to be taken.

The overdose of amlodipine can cause: marked peripheral vasodilatation, reflex tachycardia, marked systemic hypotension, which may last in time and may lead in shock.

The administration of active charcoal in healthy volunteers immediately after or up to 2 hours after taking amlodipine 10 mg, has shown a significant decrease of the absorption of amlodipine.

Gastric emptying may be valid in some cases, and also cardiovascular assistance is recommended, including control of the cardiac and respiratory function, the uplifting of the limbs, attention on the circulating fluid volume.

The use of a vasoconstrictor may be useful in the return of the vascular tone and blood pressure, on the condition that it is not contraindicated. Giving intravenous calcium gluconate may be useful to oppose the blocking effect in the calcium channels.

Since amlodipine binds highly with plasmatic proteins, dialysis may not be useful.

If you forget to take Proamlo

If you forget a dose (or more doses), take the following dose when it is time to take it usually. Do not take a double dose (or higher) to make up for the forgotten dose (doses).

If you stop taking Proamlo

You must continue taking the drug as long as your doctor recommends you. The interruption of the treatment may cause worsening of your health conditions.

If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other drugs, Proamlo can cause side effects, however not everyone manifests them. Sometimes they are serious, sometimes not. Do not be alarmed by this list of possible side effects. You may not experience any of them.
Proamlo is well tolerated from the body. The slow start of the action reduces the side effects that may appear as a result of the immediate decrease of blood pressure.

Common or very common side effects: abdominal pain, dizziness, fatigue, flushed face, headache, nausea, edema, palpitations, somnolence, sleep disturbances, asthenia, dyspnea, gastrointestinal disturbances, muscle cramps, visual disturbances, constipation.

Uncommon side effects: alopecia, arthralgia, back pain, chest pain, dry mouth, vomiting, gynecomastia, hypotension, impotence, mood and behavioral changes, myalgia, paresthesia, pruritus, purpura, rashes, rhinitis, skin discoloration, increased sweating, syncope, taste disturbances, tinnitus, tremor, urinary disturbances, weight changes, arrhythmias, coughing, anxiety.

Rare side effects: confusion.

Very rare side effects: angioedema, cholestasis**,** gastritis, gingival hyperplasia, hepatitis, hyperglycemia, jaundice, myocardial infarction, pancreatitis, peripheral neuropathy, tachycardia, thrombocytopenia, urticaria, vasculitis, leukocytopenia, muscle tone increased, photosensitivity reaction, Stevens-Johnson syndrome, erythema multiforme.

Important changes in the laboratory tests have not been reported.

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PROAMLO

Keep out of the reach and sight of children.

Store in the original packaging.

Do not use Proamlo after the expiry date stated on the package.

Do not store above 25ºC.

6. FURTHER INFORMATION

What Proamlo contains

The active substance of Proamlo 5 mg is Amlodipine besilate.

Each tablet contains 7 mg of amlodipine besilate equivalent with 5 mg amlodipine.

The excipients are: pregelatinized starch, microcrystalline cellulose, colloidal anhydrous silica, talc, magnesium stearate.

Content of the packaging

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in November 2023.