PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrMAR-AMLODIPINE

Amlodipine Besylate Tablets

Read this carefully before you start taking **MAR-AMLODIPINE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MAR-AMLODIPINE**.

What is MAR-AMLODIPINE used for?

MAR-AMLODIPINE is used in adults and children 6 years of age and older to:

- Treat high blood pressure (hypertension), or
- Manage a type of chest pain called angina.

MAR-AMLODIPINE can be used by itself or with other medicines to treat these conditions.

How does MAR-AMLODIPINE work?

MAR-AMLODIPINE belongs to a group of drugs called "calcium channel blockers".

MAR-AMLODIPINE relaxes your blood vessels, which lets your blood flow more easily. This helps to lower your blood pressure.

MAR-AMLODIPINE controls chest pain by improving the supply of blood and oxygen to the heart. This reduces the amount of work that your heart has to do.

What are the ingredients in MAR-AMLODIPINE?

Medicinal ingredients: Amlodipine besylate

Non-medicinal ingredients: Colloidal silicon dioxide, dibasic calcium phosphate anhydrous, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

MAR-AMLODIPINE comes in the following dosage forms:

Tablets: 2.5 mg, 5 mg and 10 mg amlodipine (as amlodipine besylate).

Do not use MAR-AMLODIPINE if:

- You are allergic to amlodipine, or to any of the non-medicinal ingredients in MAR-AMLODIPINE.
- You have ever had an allergic reaction to a similar type of drug.
- You have very low blood pressure (less than 90 mmHg systolic).
- You have been diagnosed with aortic stenosis (narrowing of the aortic heart valve).
- You have been diagnosed with unstable heart failure after a heart attack.
- You experience shock including cardiogenic shock.
- You are breast-feeding. Do not breast-feed while taking MAR-AMLODIPINE.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MAR-AMLODIPINE. Talk about any health conditions or problems you may have, including if you:

- Ever had heart or blood vessel diseases.
- Have poor blood circulation in the brain.
- Have liver or kidney problems.
- Are pregnant, think you may be pregnant, or plan to become pregnant.
- Are 65 years of age or older.

Other warnings you should know about:

Low Blood Pressure: MAR-AMLODIPINE may occasionally cause low blood pressure (hypotension). Your healthcare professional will monitor your blood pressure, especially if you have had a stroke or take other medications to lower your blood pressure.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not take MAR-AMLODIPINE if you are already taking medications known as "strong inhibitors of CYP 3A4". These include:

- Clarithromycin and erythromycin (antibiotic medications)
- "Azole" drugs such as ketoconazole and itraconazole (antifungal medications)
- Ritonavir (a medication used in the treatment of HIV)

Taking MAR-AMLODIPINE with any of these medications may cause serious drug interactions. If you are unsure if you are taking any of these medications, ask your healthcare professional.

The following may interact with MAR-AMLODIPINE:

- Cyclosporin (used to suppress the immune system)
- Diltiazem and beta-blockers (used to lower blood pressure)
- Quinidine, flecainide and propafenone (used to treat heart rhythm problems)
- Terfenadine (an antihistamine)
- Warfarin (used to prevent blood clots)
- Sildenafil (used to treat erectile dysfunction)
- Statin drugs such as simvastatin or atorvastatin (used to treat high cholesterol)
- Tacrolimus and sirolimus (anti-rejection drugs)
- Temsirolimus and everolimus (medications used in cancer treatment)
- Dantrolene (a muscle relaxant)
- Antacids
- Benzodiazepines (a type of sedative)
- Imipramine (an antidepressant)
- Theophylline (used to treat breathing problems)
- Phenobarbital and phenytoin (used to treat seizures)
- Rifampin (an antibiotic)

- St-John's Wort
- Grapefruit. Do not eat grapefruit or drink grapefruit juice while on MAR-AMLODIPINE.

How to take MAR-AMLODIPINE:

- Take MAR-AMLODIPINE exactly as your healthcare professional tells you
- To help you remember to take your medication, try to take MAR-AMLODIPINE at the same time each day
- Do NOT stop taking your medication without talking to your healthcare professional first

Usual dose:

For both high blood pressure and chest pain, the usual starting dose is 5 mg once daily. If necessary, your healthcare professional may increase your dose to a maximum dose of 10 mg once daily.

Use in patients with liver disease: The usual starting dose is 2.5 mg once daily. Your healthcare professional may increase your dose if necessary.

Use in children (6 to 17 years old): The usual starting dose is 2.5 mg to 5 mg once daily.

Overdose:

Signs of an overdose may include:

- Prolonged low blood pressure
- Very fast heartbeat

If you think you, or a person you are caring for, have taken too much MAR-AMLODIPINE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as you remember. If it has been more than 12 hours since you missed your last dose, skip the missed dose and continue with the next dose at your regular time. Do not take double doses.

What are possible side effects from using MAR-AMLODIPINE?

These are not all the possible side effects you may have when taking MAR-AMLODIPINE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Headaches
- Tiredness, extreme sleepiness, insomnia
- Stomach pain, nausea
- Dizziness
- Flushing of the face
- Constipation, diarrhea, indigestion

- Muscle cramps
- Weak muscles
- Nervousness
- Shortness of breath

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
COMMON			
Edema: Unusual swelling of the arms, hands, legs, feet or ankles, face or airway passages	✓		
UNCOMMON			
Allergic Reactions: Rash, hives, swelling of the face, lips, tongue or throat, difficulty breathing or swallowing, wheezing, nausea and throwing up			✓
Arrhythmia (abnormal heart rhythms): Rapid, slow or irregular heartbeat		✓	
Erectile Dysfunction (problems getting or keeping an erection)		✓	
Gynecomastia (enlargement of breast tissue in men)		✓	
Hypotension (low blood pressure): Dizziness, fainting, light-headedness, blurred vision, nausea, vomiting (may occur when you go from lying or sitting to standing up)	✓		
Liver Disorder: Yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite		✓	
Myocardial Infarction (heart attack): pressure or squeezing pain in the chest, jaw, left arm, between the shoulder blades or upper abdomen, shortness of breath, dizziness, fatigue, light-			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat			
Worsening Angina (chest pain): discomfort in the shoulder, arm, back, throat, jaw or teeth; pain or pressure in the chest		✓	
UNKNOWN FREQUENCY			
Extrapyramidal Symptoms (problems with body movement): Muscle stiffness, body spasms, tremors, restlessness, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store MAR-AMLODIPINE at room temperature (between 15-30°C). Protect from light. Keep out of reach and sight of children.

If you want more information about MAR-AMLODIPINE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); Marcan Pharmaceuticals Inc.'s website: www.marcanpharma.com, or by calling 1-855-627-2261.

This leaflet was prepared by Marcan

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