

CONSUMER INFORMATION

Pr ADALAT® XL®

Nifedipine extended-release tablets Bayer Standard

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ADALAT XL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ADALAT® XL® (nifedipine extended-release tablets) is used for:

High Blood Pressure

There are two numbers used for measuring blood pressure: systolic and diastolic. The systolic number (stated first) represents the maximum pressure of the heart muscle contraction while the heart is beating. The diastolic number (listed second) measures the basic resting pressure when the heart is refilled between beats.

Blood pressure readings lower than 120 mmHg systolic and 80 mmHg diastolic are considered to be normal for adults. Patients with values above 139 mmHg systolic and 89 mmHg diastolic are regarded as having high blood pressure.

ADALAT XL may be used in patients to manage mild to moderate high blood pressure.

Stable Angina

Angina is chest pain or discomfort that occurs when your heart muscle does not get enough blood. Angina may feel like pressure or a squeezing pain in your chest. The pain may also occur in your shoulders, arms, neck, jaw, or back. It may also feel like indigestion.

Angina is a symptom of coronary heart disease (CAD), the most common type of heart disease. CAD occurs when plaque builds up in the coronary arteries. This buildup of plaque is called atherosclerosis. As plaque builds up, the coronary arteries become narrow and stiff. Blood flow to the heart is reduced. This decreases the oxygen supply to the heart muscle.

Stable angina is the most common type of angina. It occurs when the heart is working harder than usual.

ADALAT XL may be used in patients to manage chronic stable angina.

What it does:

ADALAT XL manages high blood pressure and chronic stable angina. It is called a “calcium channel blocker”. Although the mechanism by which ADALAT XL reduces blood pressure and relieves angina is not fully known, it is believed to be brought about as a result of the ability of ADALAT XL to widen and relax blood vessels.

When it should not be used:

You should not use ADALAT XL if the following applies:

- you have had an allergic reaction to nifedipine or to any of the nonmedicinal ingredients (see What the nonmedicinal ingredients are)
- you are pregnant, breastfeeding, or a woman of childbearing age
- you have severe low blood pressure
- you are taking the medicine rifampicin

See also **SIDE EFFECTS AND WHAT TO DO ABOUT THEM.**

What the medicinal ingredient is:

ADALAT XL contains nifedipine.

What the nonmedicinal ingredients are:

ADALAT XL also contains cellulose acetate, hydroxypropyl cellulose, hydroxypropyl methylcellulose 2910, magnesium stearate, pharmaceutical shellac, polyethylene glycol 3350, polyethylene oxide, propylene glycol, red ferric oxide, sodium chloride, synthetic black iron oxide, and titanium dioxide.

What dosage forms it comes in:

The medication in ADALAT XL is packed within a nonabsorbable shell that has been specially designed to slowly release the drug so the body can absorb it.

ADALAT XL comes in strengths of 20 mg, 30 mg, or 60 mg tablets. ADALAT XL tablets are dusty rose.

WARNINGS AND PRECAUTIONS

Reactions to the drug in ADALAT *XL* vary from person to person. This may impair your ability to drive or to operate machinery, particularly at the start of treatment, when changing the medication, or in combination with alcohol.

Your doctor will have asked you many questions about your health, lifestyle, and medications before recommending ADALAT *XL*. That is why it is very important that you tell your doctor all such information.

If you have forgotten to tell your doctor about any of the following, call your doctor or pharmacist before you take this medicine (or any medicine):

- you are pregnant or breastfeeding
- you have heart failure, liver disease, kidney disease, or coronary artery disease
- you have unstable angina (sudden chest pain that occurs at rest and gets increasingly worse)
- you have recently had a heart attack or you have a heart condition called aortic stenosis (narrowing of a valve in your heart)
- you have pre-existing gastrointestinal narrowing disease
- you have diabetes
- you have a history of poor blood circulation in the brain

INTERACTIONS WITH THIS MEDICATION

Some medicines may interact with ADALAT *XL*. Let your healthcare professional know what other medicines (including over-the-counter medicines, vitamins, and herbal products) you are taking.

If you have forgotten to tell your doctor about any of the following, call your doctor or pharmacist before you take this medicine (or any medicine) if you are receiving:

- azole antifungals (ketoconazole, itraconazole or fluconazole)
- cyclosporine
- carbamazepine
- cimetidine
- diltiazem
- digoxin
- erythromycin
- fluoxetine
- HIV protease inhibitors (indinavir, nelfinavir, ritonavir, saquinavir, or amprenavir)
- nefazodone
- phenobarbital

- phenytoin
- quinidine
- quinupristin/dalfopristin
- tacrolimus
- rifampicin
- valproic acid

DO NOT eat grapefruit or drink grapefruit juice while you are using this medicine.

PROPER USE OF THIS MEDICATION

Usual Dose

Your doctor will tell you how much of this medicine to use and how often. Your dose may need to be changed several times in order to find out what works best for you. Follow your doctor's treatment plan exactly so that you reach and maintain your blood pressure targets, and get relief from angina. Do not use more medicine or use it more often than your doctor tells you to.

You can take this medication with or without food.

Do not discontinue a medication on your own. If you have a problem with a drug, always tell your doctor.

You must swallow ADALAT *XL* tablets whole. Do not chew, divide or crush the tablets. This can result in a large immediate release of the drug.

The medication in ADALAT *XL* is packed within a nonabsorbable shell that has been specially designed to slowly release the drug over 18 hours so that the body can absorb it. The shell will pass into your stool after your body has absorbed the medicine. This is normal and is nothing to worry about.

See also **ABOUT THIS MEDICATION**: When it should not be used; and **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**.

Missed Dose

If you miss a dose or forget to use your medicine, use it as soon as you can. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose. Do not use extra medicine to make up for a missed dose unless instructed by your doctor.

Overdose

In case of accidental overdose contact a healthcare practitioner, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

ADALAT XL can cause unwanted side effects. The most common side effects include swelling of tissues (edema), headaches, chest pain (angina pectoris), low blood pressure, dizziness, nausea, and constipation.

You should call your doctor if you experience any of the following:

- nausea
- vomiting

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / Effect		Talk with your doctor or pharmacist		Stop taking drug and seek emergency treatment
		Only if severe	In all cases	
Common	Wheezing or trouble breathing			✓
	Chest tightness, chest pain (angina pectoris)			✓
	Abdominal cramps		✓	
	Vomiting		✓	
	Diarrhea		✓	
	Irregular heartbeat			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / Effect		Talk with your doctor or pharmacist		Stop taking drug and seek emergency treatment
		Only if severe	In all cases	
Uncommon	Allergic reactions: difficulty breathing or swallowing, rash or hives (redness, intense itching and burning), swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs			✓
	Constipation		✓	

This is not a complete list of side effects. For any unexpected effects while taking ADALAT XL, contact your doctor or pharmacist.

HOW TO STORE IT

ADALAT XL should be stored at room temperature (15-30°C). Protect from light and humidity.

Keep all medicine away from children and never share your medicine with anyone.

Ask your pharmacist, doctor, or health caregiver about the best way to dispose of any outdated medicine or medicine no longer needed.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

Fax toll-free to 1-866-678-6789, or

Mail to: Canada Vigilance Program

Health Canada

Postal Locator 0701C

Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained at <http://www.bayer.ca> or by contacting the sponsor, Bayer Inc., at: 1-800-265-7382 or canada.medinfo@bayer.com.

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