

PART III: CONSUMER INFORMATION

Fr Atacand[®] Plus

(candesartan cilexetil/hydrochlorothiazide tablets)

This leaflet is part III of a three-part "Product Monograph" published when ATACAND[®] PLUS was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ATACAND PLUS. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ATACAND PLUS is used to treat hypertension (high blood pressure).

You may not experience any signs of high blood pressure. If high blood pressure is not treated, damage may result to vital organs such as the heart or the kidneys. High blood pressure can lead to strokes, heart attacks, heart failure, kidney failure, or blindness. It is important to take ATACAND PLUS as directed by your doctor.

What it does:

ATACAND PLUS is the brand name for this drug, which is a combination of an angiotensin II AT₁ receptor blocker (candesartan cilexetil) and a diuretic (hydrochlorothiazide). Candesartan cilexetil and hydrochlorothiazide work together to lower high blood pressure.

- The candesartan cilexetil ingredient of ATACAND PLUS lowers blood pressure by specifically blocking a naturally occurring substance called angiotensin II. Blocking angiotensin II relaxes the arteries, letting the blood flow more freely, thereby lowering the blood pressure.
- The hydrochlorothiazide ingredient of ATACAND PLUS works by making your kidneys pass more water and salt.

When it should not be used:

You should not take ATACAND PLUS if:

- You are allergic to "non-medicinal" substances like food products, preservatives, or dyes, which may be present in ATACAND PLUS tablets (see What the nonmedicinal ingredients are).
- You have ever had a bad, unusual or allergic reaction to candesartan cilexetil or hydrochlorothiazide.
- You are not producing urine.

What the medicinal ingredient is:

Candesartan cilexetil and hydrochlorothiazide.

What the nonmedicinal ingredients are:

Most medicines contain more ingredients than just the active drug. These ingredients are needed to keep medicines in a form that you can swallow. Check with your doctor if you think you might be allergic to any of the following items (listed in alphabetical order): Calcium carboxymethylcellulose, hydroxypropyl cellulose, iron oxide, lactose, magnesium stearate, maize starch and polyethylene glycol.

What dosage forms it comes in:

ATACAND PLUS is available as tablets: 16 mg / 12.5 mg, 32 mg / 12.5 mg and 32 mg / 25 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

ATACAND PLUS should not be used during pregnancy. If you discover that you are pregnant while taking ATACAND PLUS, stop the medication and please contact your physician.

Before you start ATACAND PLUS be sure you have told your doctor:

If you are pregnant, breast feeding or thinking about becoming pregnant.

Taking ATACAND PLUS during pregnancy can cause injury and even death to your baby. This medicine should not be used during pregnancy. If you are planning to become pregnant while taking ATACAND PLUS, contact your doctor immediately.

It is possible that ATACAND PLUS passes into breast milk. You should discuss with your doctor about taking ATACAND PLUS while breast feeding.

About all health problems you have or have had in the past, including any heart, liver or kidney problems.

If you have diabetes, gout or lupus erythematosus.

If you are taking a diuretic therapy (water pills) or are on salt restrictive diet.

If you are undergoing dialysis.

If you are vomiting or have diarrhea.

The treatment of high blood pressure may lead to dizziness or weariness in some patients. Make sure you are not affected in this way before driving or operating machines.

If you are currently taking ATACAND PLUS and are going to have an operation, be sure to tell your doctor or dentist about your medication before you are given an anaesthetic.

INTERACTIONS WITH THIS MEDICATION

Before taking ATACAND PLUS be sure your doctor knows about all medicines you take, including ones you can buy without a prescription. If you visit more than one doctor make sure that each knows about all the medicines you are taking.

Drugs that may interact with ATACAND PLUS include:

- Other medicines used to lower blood pressure, including diuretics (water pills);
- Potassium-sparing diuretics, potassium supplements or potassium-containing salt substitutes;
- Lithium therapy;
- Digoxin;
- Medications to treat diabetes including insulin;
- Corticosteroids;
- Nonsteroidal anti-inflammatory agents (NSAIDs);
- Allopurinol (anti-gout treatment);
- Amantadine;
- Cytotoxic drugs (cancer therapy);
- Cholestyramine;
- Anticholinergic agents such as atropine and biperiden;
- Calcium or vitamin D supplements;
- Cyclosporine

Sedatives, tranquilizers, narcotics and alcohol may increase the blood-pressure lowering effect of ATACAND PLUS, so tell your physician or pharmacist if you are taking any of these.

PROPER USE OF THIS MEDICATION

Remember, you may not notice any signs of high blood pressure. **Therefore, it is important to take ATACAND PLUS even when you feel well.** A constant amount of drug is needed in your body to control your blood pressure. **Do not stop taking ATACAND PLUS on your own.**

Usual Dose:

Take ATACAND PLUS exactly as your doctor tells you. Do not miss doses or take extra doses, unless your doctor tells you. If you are not clear about the directions, ask your doctor or pharmacist.

The dosage of ATACAND PLUS is individualized.

ATACAND PLUS is not for initial therapy. You must first be stabilized on the individual components (candesartan cilexetil and hydrochlorothiazide) of ATACAND PLUS. If your dosage matches the dosages in ATACAND PLUS, your doctor may prescribe one tablet ATACAND PLUS taken once a day (instead of each component as a separate pill).

ATACAND PLUS is not for use in children under 18 years of age.

Try to take ATACAND PLUS with something you do regularly each day; for example, upon waking or at breakfast. This will help you remember each dose.

ATACAND PLUS may be taken with food or on an empty stomach, but it should be taken consistently the same way each day.

Swallow ATACAND PLUS with a glass of water.

To help you keep track of your doses, ATACAND PLUS comes in a Compliance Pack with days of the week printed on the back of the blister. Start with the tablet that matches the day of the week and continue taking them in order until they are all finished.

There are 14 days of labeled tablets in each blister, with one extra to make 15. All 15 tablets, including the one labeled "Take this tablet last", are exactly the same. Once you have finished the 14 labeled tablets take the one marked "Take this tablet last" before starting your next blister pack.

Remember to get a new prescription from your doctor or a refill from your pharmacy a few days before all your tablets are taken.

The package protects each tablet. When you first open the package, if you find any damage to the plastic seal or foil which exposes the tablet, ask your pharmacist to check the package.

Do not transfer ATACAND PLUS to other pill containers. To protect your ATACAND PLUS tablets, keep them in the original package.

Overdose:

If you take more ATACAND PLUS than you should, contact a doctor, the Regional Poison Control centre or pharmacist immediately.

Missed Dose:

If you miss a dose of ATACAND PLUS and remember within 12 hours, you should take your usual dose as soon as possible. Then go back to your regular schedule. But if it is more than 12 hours when you remember, do not take the missed dose. Just take the next dose on time.

Never take a double dose of ATACAND PLUS to make up for missed tablets. If you still have questions or concerns, check with your doctor or pharmacist to see what you should do.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its effects on controlling blood pressure, ATACAND PLUS, like any medication, may cause side effects. These side effects are usually mild and should go away as your body gets used to ATACAND PLUS.

It is important that you keep your doctor informed if you suspect any side effects.

Effects that have been experienced include headache, throat infections, back pain and dizziness.

Side effects such as muscle pain, muscle weakness, muscle inflammation and rhabdomyolysis (a muscle-wasting disease), in rare cases leading to kidney failure, have been reported with the use of angiotensin II receptor blockers, the class of drugs to which a component of ATACAND PLUS belongs.

Medicines affect different people in different ways. Just because side effects have occurred in other patients does not mean you will get them. Discuss how you feel on ATACAND PLUS with your doctor and pharmacist. **Do not stop taking ATACAND PLUS on your own.**

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 medical assistance
		Only if severe	In all cases	
Rare	Allergic reactions: swelling of the face, lips, tongue and/or throat; rash or other skin reactions			X
	Jaundice (yellow skin and/or eyes)			X
	Muscle pain that you cannot explain, muscle tenderness or weakness, generalized weakness		X	
	Dark/brown urine		X	

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

HOW TO STORE IT

- Although the ATACAND PLUS tablets are protected in their package, it is best to keep the package at normal room temperature (15°C to 30°C) and in a dry place. Do not keep ATACAND PLUS in the bathroom.
- **Keep ATACAND PLUS out of sight and out of reach of children.** Never take medicine in front of small children as they will want to copy you.
- Do not keep or use ATACAND PLUS after the expiry date indicated on the package. Unused medicines, which you know you will no longer need, should be carefully discarded. You may wish to seek advice from your pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program, collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
 By toll-free fax: 866-678-6789
 Online: www.healthcanada.gc.ca/medeffect
 By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety and Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

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

MORE INFORMATION

All drugs can have both helpful and harmful effects. Both depend on the person and his or her health condition. This leaflet alerts you to some of the times you should call your doctor. Other situations which cannot be predicted may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about ATACAND PLUS.

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing. For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at:
www.astrazeneca.ca,
 or by contacting the sponsor, AstraZeneca Canada Inc. at:
 Customer Inquiries – 1 (800) 668-6000,
 Renseignements – 1 (800) 461-3787.

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