

ADVANT TABLETS

Candesartan Cilexetil (8mg, 16mg)

Consumer Medication Information Leaflet (RiMUP)

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What Advant is used for

This medicine is used for:

- Treating high blood pressure (hypertension) in adult patients.
- Treating adult heart failure patients with reduced heart muscle function, in addition to Angiotensin Converting Enzyme (ACE) inhibitors or when ACE inhibitors cannot be used (ACE inhibitors are a group of medicines used to treat heart failure and high blood pressure).

How Advant works

Advant belongs to a group of medicines known as angiotensin II receptor antagonists. It works by making your blood vessels relax and widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood to all parts of your body.

Before you use Advant

- When you must not use it

- If you are allergic (hypersensitive) to candesartan cilexetil or any of the other ingredients of Advant.
- If you are more than 3 months pregnant (it is also better to avoid Advant in early pregnancy).
- If you have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Advant.

- Before you start use it

Before you take, or whilst you are taking Advant, tell your doctor.

- If you have heart, liver or kidney problems, or are on dialysis.
- If you have recently had a kidney transplant.
- If you have low blood pressure.
- If you have ever had a stroke.
- If you think you are (or might become) pregnant.

Your doctor may want to see you more often and do some tests if you have any of these conditions.

If you are going to have an operation, tell your doctor or dentist that you are taking Advant. This is because Advant, when combined with some anaesthetics, may cause a drop in blood pressure.

Use in black patients:

The antihypertensive effect of candesartan is less in black than non-black patients. Consequently, up-titration of candesartan and concomitant therapy may be more frequently needed for blood pressure control in black than non-black.

Use in children and adolescents:

The safety and efficacy of candesartan have not been established in children and adolescents (under 18 years of age).

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

The antihypertensive effect of candesartan may be enhanced by other medicinal products with blood pressure lowering properties, whether prescribed as an antihypertensive or prescribed for other indications.

As with ACE inhibitors, concomitant use of Angiotensin II receptor antagonists and NSAIDs may lead to an increased risk of worsening of renal function, including possible acute renal failure, and an increase in serum potassium,

especially in patients with poor pre-existing renal function. The combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring renal function after initiation of concomitant therapy, and periodically thereafter.

How to use Advant

- How much to use

The recommended initial and maintenance dose of candesartan is 8mg once daily. In patients who require further blood pressure reduction, the dose may be increased to 16mg once daily. If blood pressure is not sufficiently controlled after 4 weeks of treatment with 16 mg once daily, the dose may be further increased to a maximum of 32mg once daily. If blood pressure control is not achieved with this dose, alternative strategies should be considered.

Therapy should be adjusted according to blood pressure response. The maximal antihypertensive effect is attained within 4 weeks of initiation of treatment.

Use in the Elderly

No initial dosage adjustment is necessary for elderly patients.

Use in Impaired Renal Function

No initial dosage adjustment is necessary in patients with mild to moderate renal impairment (i.e., creatinine clearance >30 ml/min/1.73 m² BSA). In patients with severe renal impairment (i.e., creatinine clearance <30 ml/min/1.73 m² BSA), the clinical experience is limited and a lower initial dose of 4 mg should be considered.

Use in Impaired Hepatic Function

No initial dosage adjustment is necessary in patients with mild to moderate chronic liver disease. There is only limited experience available in patients with severe hepatic impairment and/or cholestasis. A lower initial dose of 4 mg should therefore be considered in these patients.

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Concomitant Therapy

Candesartan may be administered with other antihypertensive agents, such as thiazide type diuretic.

- When to use it

Use as directed by your doctor or pharmacist. Advant should be taken once daily with or without food.

- How long to use it

Continue taking Advant for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine.

Based on pharmacological considerations, the main manifestation of an overdose is likely to be low blood pressure and dizziness.

If the symptoms of overdose occur, symptomatic treatment should be instituted and vital signs monitored. Contact your doctor even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Your doctor will decide the most suitable treatment for you.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Advant
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Advant to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Advant is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage.

It is not known whether candesartan is excreted in human milk. However, candesartan is excreted in the milk of lactating rats. Because of the potential for adverse effects on the nursing infant Candesartan should not be given during breast-feeding.

Side effects

Like all medicines, Advant can cause side effects, although not everybody gets them. It is important that you are aware of what these side effects may be.

Advant may cause a reduction in number of white blood cells. Your resistance to infection may be decreased and you may notice tiredness, an infection or a fever. If this happens contact your doctor. Your doctor may occasionally do blood tests to check whether Advant has had any effect on your blood (agranulocytosis). Other possible side effects include:

Common (affects 1 to 10 users in 100)

- Feeling dizzy / spinning sensation.
- Headache.
- Respiratory infection.
- Low blood pressure. This may make you feel faint or dizzy.
- Changes in blood test results:

- An increased amount of potassium in your blood, especially if you already have kidney problems or heart failure. If this is severe you may notice tiredness, weakness, an irregular heart beat or pins and needles.

- Effects on how your kidneys work, especially if you already have kidney problems or heart failure.

In very rare cases, kidney failure may occur.

Very rare (affects less than 1 user in 10,000)

- Swelling of the face, lips, tongue and/or throat.
- A reduction in your red or white blood cells. You may notice tiredness, an infection or a fever.
- Skin rash, lumpy rash (hives).
- Itching.
- Back pain, pain in joints and muscles.
- Changes in how your liver is working, including inflammation of the liver (hepatitis). You may notice tiredness, yellowing of your skin and the whites of your eyes and flu like symptoms.
- Nausea.
- Changes in blood test results:
- A reduced amount of sodium in your blood. If this is severe then you may notice weakness, lack of energy, or muscle cramps.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Advant

- Storage

Store below 30°C. Protect from sunlight and moisture. The expiration date refers to the product correctly stored at the required conditions.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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Product Description

- What it looks like

Advant Tablets 8mg (Candesartan Cilexetil) is a cream colored square shaped tablet marked bisect line on one side and other side is plain.

Advant Tablets 16mg (Candesartan Cilexetil) is a white colored square shaped tablet marked bisect line on one side and other side is plain.

- Ingredients

- Active ingredient

Advant Tablets 8mg: Candesartan Cilexetil 8mg

Advant Tablets 16mg: Candesartan Cilexetil 16mg

- Inactive ingredients

Advant Tablets 8mg: Polysorbate 80, Distilled Water, Magnesium stearate, Lactose Regular, Carboxyl Methyl Cellulose Calcium, Pharmacoat 606 (HPMC), Egg Yellow Color 7652

Advant Tablets 16mg: Polysorbate 80, Distilled Water, Magnesium stearate, Lactose Regular, Carboxyl Methyl Cellulose Calcium, Pharmacoat 606 (HPMC)

- MAL number(s):

Advant Tablets 8mg: MAL07090922A

Advant Tablets 16mg: MAL07090920A

Manufacturer

Getz Pharma (Pvt.) Limited, 29-30/27, K.I.A., Karachi - 74900, Pakistan.

Product Registration Holder

LF Asia (Malaysia) Sdn Bhd (719-V)
Lot 6, Persiaran Perusahaan, Seksyen 23,
40300 Shah Alam,
Selangor Darul Malaysia

Date of revision

24/01/2014