

RASILEZ[®] FILM-COATED TABLET

Aliskiren (150 mg, 300 mg)

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What Rasilez is used for

Your medicine is called Rasilez and comes in the form of a film-coated tablet. Each tablet contains 150 mg or 300 mg of the active substance aliskiren. Rasilez belongs to a new class of medicines called “renin inhibitor”, which help to lower high blood pressure. Rasilez is used to treat high blood pressure. High blood pressure increases the workload of the heart and blood vessels. If it continues for a long time, it can damage the blood vessels of the brain, heart and kidneys, and may result in a stroke, heart failure, heart attack or kidney failure. High blood pressure increases the risk of heart attacks. Lowering blood pressure to a normal level reduces the risk of developing these disorders.

How Rasilez works

Aliskiren belongs to a new class of medicines called renin inhibitors that help to lower high blood pressure. Renin inhibitors reduce the amount of Angiotensin II, the body can produce. Angiotensin II causes blood vessels to tighten, thus increasing blood pressure. Reducing the amount of Angiotensin II allows the blood vessels to relax which lowers blood pressure. If you have any questions about how Rasilez works or why this medicine has been prescribed for you, ask your doctor.

Before you use Rasilez

Follow all the doctor’s instructions carefully. They may differ from the general information contained in this leaflet.

Your doctor may wish to have your blood tested before and at regular intervals during your treatment to check the values of potassium, magnesium, calcium, sodium, sugar, cholesterol, uric acid and the amounts of red and white cells as well as platelets. Your doctor may also monitor your kidney function.

When you must not use it

- If you are allergic (hypersensitive) to Rasilez or any of the other ingredients of Rasilez listed at the end of this leaflet. If you think you may be allergic, ask your doctor for advice.
- If you are suffering from type 2 diabetes (also called non-insulin dependent diabetes mellitus) and you are taking a special kind of medicine called Angiotensin-Receptor-Blocker (ARB) or Angiotensin-Converting-Enzyme-inhibitor (ACEI) at the same time.

If any of these apply to you, tell your doctor and do not take Rasilez. Your doctor will decide whether this medicine is suitable for you.

Pregnancy and breast-feeding

You should not take Rasilez if you are pregnant or planning to become pregnant. It is important to check with your doctor immediately if you think you may have become pregnant or are planning to become pregnant. Your doctor will discuss with you the potential risk of taking Rasilez during pregnancy. Tell your doctor if you are breast-feeding. You should not breast-feed if you are taking Rasilez, as it might be harmful for your baby.

Before you start to use it

Inform your doctor before taking Rasilez

- If your body have marked dehydration, such as excessive vomiting or diarrhea
- If you have some salt depletion problem in your body
- If you have an impaired kidney function with symptoms such as decreased urinary output (including other conditions that might impact the kidney function) or a narrowing / blockage of the artery that supplies blood to the kidney. This is especially important, if you are currently taking ACEI medicines like perindopril (for high blood pressure), ARB medicines like irbesartan (for high blood pressure) and NSAID medicines like celecoxib (a painkiller). Your doctor may check your electrolyte levels (mainly potassium) in your blood and also check your kidney function.
- If you suffer from low blood pressure at the beginning of the treatment, consult your doctor.

If any of these apply to you, tell your doctor before you take Rasilez.

Older people (age 65 and over)

You can take Rasilez if you are 65 years of age or older.

Children/adolescents

Rasilez film-coated tablets are not recommended for use in patients under 18 years of age.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. It may be necessary to change the

dose, to take other precautions, or in some cases to stop taking one of the medicines.

This applies to both prescription and non-prescription medicines, especially:

- Medicines belonging to classes of medicines known as ARBs or ACEIs, which help to control high blood pressure.
- Ciclosporin, a medicine used in transplantation to prevent graft rejection or for other conditions, e.g.:
Rheumatoid arthritis or atopic dermatitis.
- Itraconazole and ketoconazole, medicines used to treat fungal infections.
- Potassium-sparing diuretics, potassium-containing medicines, potassium supplements, or salt substitutes containing potassium.
- Furosemide, used to increase the amount of urine (diuretic).
- Atorvastatin, a medicine used to treat high cholesterol.
- Verapamil, a medicine used to treat high blood pressure or heart diseases.
- Certain types of pain killers called non-steroidal anti-inflammatory medicines (NSAIDs) or Selective Cyclooxygenase-2 Inhibitors (Cox-2 Inhibitors).

How to use Rasilez

Follow your doctor's instructions carefully. Do not exceed the recommended dose.

Patients who have high blood pressure often do not notice any signs of this problem. Many may feel quite normal. It is very important that you take this medicine exactly as your doctor tells you in order to get the best results and reduce the risk of side effects. Keep your appointments with the doctor even if you are feeling well.

How much to use

The usual starting dose is one 150 mg film-coated tablet once a day. In some cases, your doctor may prescribe a higher dose (e.g. 300 mg film-coated tablet) or an additional medicine used to treat high blood pressure.

Your doctor will tell you exactly how many tablets of Rasilez to take.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

When to use it

Swallow Rasilez tablets whole with a small amount of water. Do not chew or crush the tablets.

Rasilez tablets may be taken with or without food.

How long to use Rasilez

Follow your doctor's instructions exactly. Your doctor will tell you for how long you should take Rasilez.

If you forget to use Rasilez

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, you should simply take the next tablet at the usual time. Do not take a double dose to make up for a forgotten dose.

If you use too much (overdose)

If you have accidentally taken too many tablets, talk to your doctor right away. You may require medical attention.

While you are using Rasilez

Things you must do

If you are experiencing difficulty breathing or swallowing, tightness of the chest, hives, general rash, swelling, itching, dizziness, vomiting, abdominal pain (signs of a severe allergic reaction) or swelling mainly of the face and throat (sign of angioedema), stop taking Rasilez and contact your doctor immediately.

Things you must not do

Do not stop taking the medication unless advised by your doctor.

Things to be careful of

Driving and using machines.

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

As with all medicines, patients taking Rasilez may experience some side effects, although not everybody gets them.

Some side effects can be serious (frequency unknown):

- Allergic reaction (hypersensitivity) with symptoms such as rash, itching, hives, difficulty breathing or swallowing, dizziness vomiting, abdominal pain (This might be sign of a severe allergic reaction called anaphylactic reaction).
- If you develop an allergic reaction involving swelling of the face, lips, throat and/or tongue which may cause difficulty in breathing and swallowing (angioedema), stop taking Rasilez and contact your doctor immediately.
- Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (this might be signs of a condition called toxic epidermal necrolysis or Stevens Johnson syndrome)
- Kidney disorder with symptoms such as severely decreased urine output. This might be signs of renal impairment or failure.
- Nausea, loss of appetite, dark colored urine or yellowing of skin and eyes (signs of liver disorder)

If you experience any of these, tell your doctor immediately.

Other Side effects:

Common side effects – likely to affect between 1 and 10 in every 100 patients:

- Diarrhea
- High levels of potassium in the blood (hyperkalemia)

Uncommon side effects – likely to affect between 1 and 10 in every 1,000 patients:

- Skin rash

Side effects with frequency unknown:

- Itching
- Skin reddening
- Dizziness
- Edema with swollen hands, ankles or feet
- Low blood pressure
- Abnormal liver function test results
- Abnormal kidney function test results
- Abnormal blood test result
- Low level of cells in blood

If any of the side effects affects you severely, 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 Rasilez

Storage

- Do not store above 30°C.
- Do not use after the expiry date shown on the box.
- Store in the original package.
- Keep out of the reach and sight of children.

Disposal

- Any unused product or waste material should be disposed of in accordance with local requirements

Product Description

What it looks like

Your medicine is called Rasilez and comes in the form of a tablet. Each tablet contains 150 mg or 300 mg of the active substance aliskiren.

150 mg : Light pink, biconvex round film-coated tablet with debossment “IL” on one side and “NVR” on the other side.

300 mg : Light red, biconvex ovaloid film-coated tablet with debossment “IU” on one side and “NVR” on the other side.

Ingredients

- Active ingredient
 - The active substance of Rasilez is aliskiren hemifumarate.
- Inactive ingredients
 - The other ingredients are microcrystalline cellulose, crospovidone, povidone, magnesium stearate, silica colloidal anhydrous, macrogol, talc, hypromellose, titanium dioxide (E171), red iron oxide (E172), black iron oxide (E172).

MAL Number

Rasilez 150mg Film-Coated Tablet: MAL20081730A

Rasilez 300mg Film-Coated Tablet: MAL20081731A

Manufacturer

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Product Registration Holder

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