

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

# Rasilez 150 mg, Rasilez 300 mg Film-coated tablets

Each film-coated tablet contains:  
Rasilez 150 mg: Aliskiren 150 mg  
Rasilez 300 mg: Aliskiren 300 mg

**Inactive ingredients:** See section 6 "Further information".

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

The medicine is not intended for children and adolescents under 18 years of age.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

Treatment of high blood pressure.

Aliskiren belongs to a class of medicines called "renin inhibitors", which helps 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.

High blood pressure increases the workload of the heart and arteries. If high blood pressure 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 and 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.

**Therapeutic group:** Agents acting on the Renin-Angiotensin system; direct inhibitor of the renin enzyme.

## 2. BEFORE USING THE MEDICINE

- ⊠ Do not use the medicine if:**
- you are allergic (hypersensitive) to the active ingredient or to any of the other ingredients in this medicine, listed in section 6 "Further information" of this leaflet. If you think you may be allergic, please ask your doctor for advice.
  - you already had angioedema (difficulties in breathing or swallowing, or swelling of the face, hands and feet, eyes, lips and/or tongue) following taking aliskiren.
  - you have hereditary or idiopathic angioedema.
  - you are in the second or third trimester of pregnancy.
  - you are taking ciclosporin (a medicine used in transplantation to prevent organ rejection or for other conditions, such as rheumatoid arthritis or atopic dermatitis) or itraconazole (a medicine used to treat fungal infections) or quinidine (a medicine used to correct heart rhythm).
  - you are suffering from diabetes or suffer from kidney function impairment and you are taking a special kind of medicine called Angiotensin Receptor Blocker (ARB) or Angiotensin Converting Enzyme inhibitor (ACEi) at the same time.
  - Do not use in children less than 2 years of age.

### Special warnings regarding the use of this medicine

- If you have 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 or throat (sign of angioedema), **stop taking Rasilez and contact the doctor straight away.**
- **Contact your doctor** if you suffer from severe and persistent diarrhea.

**⊠ Before treatment with Rasilez, tell your doctor if any of these conditions apply to you:**

- If you suffer from low blood pressure at the beginning of the treatment, consult your doctor.
- If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.
- If you suffer from an impaired kidney function with symptoms such as decreased urinary output (or other conditions that might impact the kidney function) or from a narrowing or blockage of the artery that supplies blood to the kidney. This is especially important if you are taking other drugs affecting the Renin-Angiotensin-Aldosterone system (see also section "Do not use the medicine if:" which appears above) or certain types of painkillers called non-steroidal anti-inflammatory drugs (NSAIDs) (see also section 1 "What is the medicine intended for?").
- If you are taking a diuretic (a medicine which increases the amount of urine) or medicines used to control blood pressure and acting on the Renin-Angiotensin-Aldosterone system, such as Angiotensin Receptor Blockers (ARBs) or Angiotensin Converting Enzyme inhibitors (ACEis).

- If you are pregnant or planning to become pregnant.
- If you suffer from serious congestive heart failure (a type of heart disease where the heart cannot pump enough blood around the body).

**⊠ If you are taking or have recently taken other medicines, including medicines obtained without a prescription and food supplements, tell the doctor or pharmacist.** Especially if you are taking:

- Medicines called Angiotensin Receptor Blockers (ARBs) or Angiotensin Converting Enzyme inhibitors (ACEis) (see above).
- Ciclosporin, a medicine used in transplantation to prevent organ rejection or for other conditions, such as rheumatoid arthritis or atopic dermatitis (see above section 2 "Do not use the medicine if").
- Itraconazole, a medicine used to treat fungal infections (see above section 2 "Do not use the medicine if").
- Quinidine (a medicine used to correct heart rhythm) (see above in section 2 - "Do not use the medicine if").
- Potassium-sparing diuretics, potassium-containing medicines, potassium supplements or salt substitutes containing potassium, heparin.
- Furosemide, used to increase the amount of urine (a diuretic).
- Ketoconazole, a medicine used to treat fungal infections.
- Atorvastatin, a medicine used to treat high cholesterol.
- Verapamil, a medicine used to treat high blood pressure or heart diseases.
- Certain types of painkillers called non-steroidal anti-inflammatory drugs (NSAIDs) or cyclooxygenase inhibitors (Cox inhibitors). The doctor may also check your kidney function.

### ⊠ Use of the medicine and food

The medicine should not be taken with grapefruit juice.

The tablet should be taken after a light meal, preferably at the same time each day.

### ⊠ Children and adolescents (below 18 years of age)

This medicine is intended for use in adults.

Do not use in children less than 2 years of age.

This medicine is not intended for children and adolescents under 18 years of age.

### ⊠ Pregnancy and breast-feeding

Do 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 are pregnant or are planning to become pregnant. Your doctor will discuss with you the risks of taking Rasilez during pregnancy.

Do not breast-feed while taking Rasilez, as it might be harmful for your infant.

### ⊠ Driving and using machines

Use of this medicine may cause dizziness in some people, and hence, disrupt their ability to concentrate. Before driving a vehicle, using dangerous machinery, or carrying out activities that require a high level of concentration, you should make sure you know how the medicine affects you.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

You should check with your doctor or pharmacist if you are not sure.

The dosage and the way of treatment will be determined by the doctor only. The usual starting dose is generally one 150 mg tablet, once a day. In some cases, the doctor may prescribe a higher dose (i.e., a 300 mg tablet, once daily) or an additional medicine used to treat high blood pressure.

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

**Do not exceed the recommended dose.**

### When and how to take Rasilez

Swallow the tablets whole with water. Do not chew or crush the tablets!

This medicine should be used at specific time intervals as determined by the attending doctor.

### Duration of treatment with Rasilez

The doctor will tell you how long to take Rasilez.

### Tests and follow-up

The doctor may check the electrolyte levels (mainly potassium) in your blood and also check your kidney function.

### If you took by mistake a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Medical treatment may be necessary.

### If you forgot to take this medicine

If you forget to take this medicine at the specified time, take a dose as soon as you remember and then take the next dose at its usual time. However, if it is nearly time for your next dose, take the next tablet at the usual time.

Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine without consulting the doctor.

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

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have further questions about the use of this medicine, consult the doctor or pharmacist.

## 4. SIDE EFFECTS

As with all medicines, the use of Rasilez can cause side effects in some of the users. Do not be alarmed by this list of side effects. You may not experience any of them.

**Some side effects can be serious:**

**Contact your doctor immediately in case of:**

- Allergic reaction (hypersensitivity) with symptoms such as rash, itching, hives, difficulty breathing or swallowing, dizziness.
- Renal disorder with symptoms, such as severely decreased urinary output (renal failure).
- 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 the doctor immediately.
- Rash, skin redness, blistering of the lips, eyes or mouth, skin peeling, fever (toxic epidermal necrolysis or Stevens-Johnson syndrome).
- Difficulty breathing or swallowing, tightness of the chest, hives, general rash, swelling, itching, dizziness, vomiting, abdominal pain (signs of a severe allergic reaction called anaphylactic reaction).
- Nausea, loss of appetite, dark colored urine or yellowing of skin and eyes (signs of liver disorder).

**Additional side effects:**

**Common side effects** (affecting 1-10 in every 100 patients): Diarrhea, joint pain, high level of potassium in the blood (hyperkalemia), dizziness.

**Uncommon side effects** (affecting 1-10 in every 1,000 patients): Skin rash (this may be a sign of allergic reactions or angioedema - see "Rare side effects" below), kidney problems with symptoms such as severely decreased urine output (renal failure), edema with swelling of the hands, ankles or feet, severe skin reactions (skin redness, blistering of the lips, eyes or mouth, skin peeling, fever), low blood pressure, palpitations, cough, itching, itchy skin rash (urticaria), increased liver enzymes.

**Rare side effects** (affecting 1-10 in every 10,000 patients): Severe allergic reaction (anaphylactic reaction), allergic reactions (hypersensitivity) and angioedema (the symptoms of which can include difficulties in breathing or swallowing, rash, itching, swelling of the face, hands and feet, eyes, lips and/or tongue, dizziness), increased level of creatinine in the blood, Haemoglobin decreased, skin redness, low level of cells in the blood.

**Other side effects** (with frequency unknown): dizziness with spinning or movement sensation, nausea, vomiting, liver disorder, jaundice, hepatitis.

If a side effect appears, if any of the side effects becomes worse or when you suffer from a side effect not mentioned in this leaflet, consult the doctor.

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature lower than 30°C.
- Store in the original pack.
- Protect from moisture.

## 6. FURTHER INFORMATION

**In addition to the active ingredient, the medicine also contains:**

Microcrystalline cellulose, crospovidone, povidone, magnesium stearate, silica colloidal anhydrous, hypromellose, macrogol 4000, talc, titanium dioxide, red iron oxide, black iron oxide.

**How does the medicine look and what is the content of the package:**

**150 mg tablet:** Round, biconvex, light pink film-coated tablet, with beveled edges, imprinted with "IL" on one side and "NVR" on the other side. Pack of 28 film-coated tablets.

**300 mg tablet:** Ovaloid, biconvex, light red film-coated tablet, with beveled edges, imprinted with "IU" on one side and "NVR" on the other side. Pack of 28 film-coated tablets.

- **License Holder and Address:** Novartis Pharma Services AG, 36 Shacham St., Petach-Tikva.
- **Manufacturer and Address:** Novartis Farma SpA, Torre Annunziata, Italy, for Novartis Pharma AG, Basel, Switzerland.
- This leaflet was checked and approved by the Ministry of Health in June 2015.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:  
Rasilez 150 mg: 138 80 31611  
Rasilez 300 mg: 138 81 31612