

RASILEZ HCT[®] FILM-COATED TABLET

Aliskiren/Hydrochlorothiazide (150 /12.5 mg, 150 /25 mg, 300 /12.5 mg and 300 /25 mg)

What is in this leaflet

1. What Rasilez HCT is used for
2. How Rasilez HCT works
3. Before you use Rasilez HCT
4. How to use Rasilez HCT
5. While you are using Rasilez HCT
6. Side effects
7. Storage and Disposal of Rasilez HCT
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Rasilez HCT is used for

Your medicine is called Rasilez HCT and comes in the form of a film-coated tablet. Each tablet contains two active substances, aliskiren (150 mg or 300 mg) and hydrochlorothiazide (12.5 mg or 25 mg). Both active substances lower blood pressure. Rasilez HCT is used to treat high blood pressure. High blood pressure increases the workload of the heart and arteries (blood vessels). If left untreated, high blood pressure can damage a variety of organs of the body including the heart, brain, kidney, blood vessels and eye. It may result in a stroke, heart failure, heart attack, kidney failure or damage to the retina of the eye. High blood pressure increases the risk of heart attacks. Lowering blood pressure to a desired level reduces the risk of developing these disorders.

How Rasilez HCT 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, which increases the blood pressure. Reducing the amount of angiotensin II allows the blood vessels to relax, which lowers blood pressure. Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics. Hydrochlorothiazide causes your urine output to increase, which also lowers your blood pressure.

If you have any questions about how Rasilez HCT works or why this

medicine has been prescribed for you, ask your doctor.

Before you use Rasilez HCT

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 aliskiren or hydrochlorothiazide or sulfonamides or any of the other ingredients of Rasilez HCT listed at the end of this leaflet,
- If you have inability to produce urine (anuria),
- If you are pregnant or planning to become pregnant.
- 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 without taking Rasilez HCT. If you think you may be allergic, ask your doctor for advice.

Women of child-bearing potential , pregnancy and breast-feeding

You should not take Rasilez HCT 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 HCT during pregnancy.

It is also advisable not to take Rasilez HCT during breast-feeding. If you are breast-feeding, tell your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

Inform your doctor before taking Rasilez HCT

- If your body have marked dehydration such as excessive vomiting or diarrhea.
- If you have some salt depletion problem in your body
- If you are taking a diuretic (a medicine to increase the amount of urine you produce), or medicines used to control blood pressure and acting on the Renin-Angiotensin-Aldosterone system such as ARBs or ACEIs .
- If you are taking ciclosporin (a medicine used in transplantation to prevent organ rejection or for other conditions, e.g.: Rheumatoid arthritis or atopic dermatitis) or itraconazole (a medicine used to treat fungal infections),
- If you have fever, facial rash, and joint pain, which may be signs of lupus erythematosus (or a history of this disease),
- If you have diabetes (high blood sugar),
- If you have been told you have high levels of cholesterol or triglycerides in your blood,
- If you have been told you have low levels of potassium (with or without symptoms such as muscle weakness, muscle spasms, abnormal heart rhythm) or magnesium in your blood.
- If your doctor has told you that you have low levels of sodium in your blood (with or without symptoms such as tiredness, confusion, muscle twitching, convulsions).
- If you have been told you have high level of calcium in your blood (with or without symptoms such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching).
- If your doctor has told you that you have high levels of uric acid in the blood.
- If you suffer from an impaired kidney function with symptoms such as decreased urinary output (or other conditions that might impact the renal function) or a

narrowing or blockage of the arteries that supply blood to your 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 a liver disorder,
- If you suffer from allergy or asthma

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

Older people (over 65 years)

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

Children and adolescents (below 18 years)

Rasilez HCT tablets are not recommended for use in patients under 18 years of age.

Taking other medicines

Tell your doctor or a pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes in particular:

- medicines belonging to classes of medicines known as ARBs or ACEIs, which help to control high blood pressure.
- some medicines used to treat infections such as ketoconazole, amphotericin, penicillin G,
- medicines used for oesophageal ulceration and inflammation (carbenoxolone),
- medicines used to lower blood pressure,
- potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium,
- lithium, antidepressants, antipsychotics, medicines used to treat some mental conditions,
- antiepileptics such as carbamazepine (medicines used to treat convulsions)
- medicines used to relieve pain or inflammation, especially non-steroidal anti-inflammatory agents

(NSAIDs), including Cox-2 selective inhibitors.

- cortisone-like medicines, steroids,
- digoxin or other digitalis glycosides (a heart medicine),
- muscle relaxants (medicines used during operations),
- allopurinol (anti-gout treatment),
- amantadine (a medicine used to treat -Parkinson's disease, also used to treat certain viral diseases),
- certain cancer medicines,
- anticholinergic agents (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anesthesia),
- diazoxide (used to treat low blood sugar levels),
- ciclosporin (a medicine used in transplantation to prevent organ rejection or for other conditions, e.g: Reumathoid arthritis or atopic dermatitis),
- itraconazole, a medicine used to treat fungal infections,
- insulin or antidiabetic medicines taken by mouth,
- cholestyramine and colestipol, resins used mainly to treat high levels of lipids in the blood,
- vitamin D and calcium salts,
- atorvastatin, a medicine used to treat high cholesterol,
- verapamil, a medicine used to treat high blood pressure or heart diseases,
- other medicines used to treat high blood pressure.
- barbiturates, narcotics (medicines with sleep-inducing properties) and alcohol.
- pressor amines, such as noradrenaline (substances that raise blood pressure).

How to use Rasilez HCT

Patients who have high blood pressure often do not notice any signs of this problem. Most feel quite normal. This makes it more important for you to take your medicine exactly as the doctor or pharmacist tells you and to keep your appointments with the doctor even if you are feeling well.

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

Rasilez HCT is for oral use only.

How much to use

Your doctor will tell you exactly how much of Rasilez HCT to take.

The usual dose is one Rasilez HCT (150/12.5 mg) or Rasilez HCT (300/12.5 mg) or Rasilez HCT (150/25 mg) or Rasilez HCT (300/25 mg) tablet once a day.

Do not change the dose or stop treatment without talking to your doctor.

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

When to use Rasilez HCT

Taking Rasilez HCT at the same time each day will help you remember when to take your medicine.

You can take Rasilez HCT with or without food. Swallow your tablet with a glass of water.

How long to use Rasilez HCT

Continue taking Rasilez HCT as your doctor tells you.

If you have questions about how long to take Rasilez HCT, talk to your doctor or your pharmacist.

If you forget to use Rasilez HCT

It is advisable to take your medicine at the same time each day, preferably in the morning. However, if you forget to take a dose of this medicine, take it as soon as possible. If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to. Otherwise, take the dose as soon as you remember, and then take the next tablet as you would normally. Do not take a double dose to make up for the one that you missed.

If you use too much Rasilez HCT (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 HCT

Things you must do

- If you experience faintness and/or light-headedness at the beginning

of treatment with Rasilez HCT, consult your doctor immediately.

- 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 (signs of angioedema), stop taking Rasilez HCT and contact your doctor immediately.
- If you experience a decrease in vision or eye pain. These could be symptoms of an increase of pressure in your eye and can happen within hours to weeks of taking Rasilez HCT. This can lead to permanent vision impairment, if not treated. Stop taking Rasilez HCT and immediately visit your doctor.

Things you must not do

Stopping your treatment with Rasilez HCT may cause your disease to get worse. Do not stop taking your medicine unless instructed 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 HCT may experience side effects, although not everybody gets them.

The frequency of the side effects listed below is defined using the following convention:

Common: *These side effects may affect between 1 and 10 in every 100 patients*

Uncommon: *These side effects may affect between 1 and 10 in every 1000 patients.*

Rare: *These side effects may affect between 1 and 10 in every 10,000 patients.*

Very rare: *These side effects may affect less than 1 in every 10,000 patients.*

Common:

- Diarrhea

If diarrhea affects you severely, tell your doctor.

Side effects with aliskiren or hydrochlorothiazide alone which can be serious

Aliskiren (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 (toxic epidermal necrolysis or Stevens Johnson syndrome)
- Kidney disorder with symptoms such as severely decreased urine output (renal impairment). 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.

Hydrochlorothiazide (Rare or very rare):

- Yellow eyes or skin (jaundice),
- Irregular heart beat (arrhythmia),
- Spontaneous bleeding and/or bruising, sometimes underneath the skin which is a sign of low level of blood platelets (thrombocytopenia),
- Rash, purplish-red spots, fever, itching (symptoms of an inflammation of blood vessel also called vasculitis),
- Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (toxic epidermal necrolysis, erythema multiforme),
- Facial rash, joint pain, muscle disorder, fever (lupus erythematosus),
- Severe upper stomach pain (pancreatitis),

- Fever, sore throat or mouth ulcers due to infections (leucopenia),
- Fever, sore throat, more frequent infections (agranulocytosis),
- Weakness, bruising and frequent infections (pancytopenia, aplastic anemia),
- Pale skin, tiredness, breathlessness, dark urine (hemolytic anemia),
- Rash, itching, hives, difficulty breathing or swallowing, dizziness (hypersensitivity reaction),
- Difficulty breathing with fever, coughing, wheezing, breathlessness (respiratory distress including pneumonitis and pulmonary edema)
- Severely decreased urine output (possible signs of renal disorder or renal failure)
- Decrease in vision or pain in your eyes due to high pressure (possible signs of acute angle-closure glaucoma)

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

Other possible side effects with aliskiren or hydrochlorothiazide alone

Aliskiren

Common:

- High levels of potassium in the blood (hyperkalemia)

Uncommon:

- Skin rash

Other 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 results
- Low level of cells in blood

If any of these affects you severely, tell your doctor.

Hydrochlorothiazide

Common:

- Itchy rash and other forms of rash,
- Reduced appetite,
- Nausea and vomiting,
- Faintness and/or light-headedness (which may be aggravated by alcohol, anaesthetics or sedatives),
- Inability to achieve or maintain an erection

Rare:

- Dizziness
- Increased sensitivity to the sun,
- Abdominal discomfort,
- Constipation,
- Headache,
- Sleep disturbances,
- Depression,
- Tingling or numbness,
- Vision disorder

If any of these affect you severely, tell your doctor.

Other side effects with frequency

unknown:

- Weakness (asthenia)
- Fever
- Muscle spasm

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 HCT

Storage

- Do not use after the expiry date shown on the box.
- Do not store above 30°C
- 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

Rasilez HCT is supplied as film-coated tablets in four strengths:

- Rasilez HCT film-coated tablets (150/12.5 mg) containing 150 mg aliskiren and 12.5 mg

hydrochlorothiazide. They are white, biconvex ovaloid film-coated tablets imprinted with “LCI” on one side and “NVR” on the other side

- Rasilez HCT film-coated tablet, (150/25 mg) containing 150 mg aliskiren and 25 mg hydrochlorothiazide. They are pale yellow, biconvex ovaloid film-coated tablet imprinted with “CLL” on one side and “NVR” on the other side.
- Rasilez HCT film-coated tablet, (300/12.5 mg) containing 300 mg aliskiren and 12.5 mg hydrochlorothiazide. They are violet white, biconvex ovaloid film-coated tablet imprinted with “CVI” on one side and “NVR” on the other side.
- Rasilez HCT film-coated tablet, (300/25 mg) containing 300 mg aliskiren and 25 mg hydrochlorothiazide. They are light yellow, biconvex, ovaloid film-coated tablet imprinted with “CVV” on one side and “NVR” on the other side.

Ingredients

- Active ingredients
 - The active substances of Rasilez HCT are aliskiren hemifumarate and hydrochlorothiazide
- Inactive ingredients
 - The other ingredients of Rasilez HCT are cellulose microcrystalline, crospovidone, lactose monohydrate, wheat starch, povidone, magnesium stearate, silica colloidal anhydrous, talc, hypromellose, macrogol, titanium dioxide (E 171)
 - Rasilez HCT 150 mg/25 mg and 300 mg/25 mg contain in addition iron oxide red (E172) and iron oxide yellow (E172)
 - Rasilez HCT 300 mg/12.5 mg contain in addition: iron oxide black (E 172) and iron oxide red (E 172).

MAL Number

Rasilez HCT 150/12.5mg Film-Coated Tablet: MAL20091951A

Rasilez HCT 150/25mg Film-Coated Tablet: MAL20091952A

Rasilez HCT 300/12.5mg Film-Coated Tablet: MAL20091953A

Rasilez HCT 300/25mg Film-Coated Tablet: MAL20091954A

Manufacturer

Novartis Farma S.P.A.,
Via Provinciale Schito 131, 80058
Torre Annunziata, Italy.

Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd.
Level 22, Tower B, Plaza 33,
No. 1, Jalan Kemajuan, Seksyen 13,
46200 Petaling Jaya, Selangor

Date of revision

26/05/2015

Serial Number

BPFK(R4/1)/210515/00115