If you are allergic to ramipril, any other ACE inhibitor medicine or any of the ingredients of this medicine listed in section 6. Signs of an allergic reaction may include a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.

If you have ever had a serious allergic reaction called "angioedema." The signs include hives, itching, red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing.

If you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults.

If you are having dialysis or any other type of blood filtration. Depending on the machine that is used, TRITACE may not be suitable for you.

If you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis)

During the last 6 months of pregnancy (see section below on "Pregnancy and breast-feeding")

If your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment.

If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Do not take TRITACE if any of the above apply to you.

If you are not sure, talk to your doctor before taking TRITACE.

WARNINGS AND PRECAUTIONS

Talk to your doctor or pharmacist before taking TRITACE:

If you have heart, liver or kidney problems

If you have lost a lot of body salts or fluids (through being sick (vomiting), having diarrhoea, sweating more than usual, being on a low salt diet, taking diuretics (water tablets) for a long time or having had dialysis)

If you are going to have treatment to reduce your urine volume (diuresis) (this can happen with some medicines such as thiazides or other diuretics which help reduce the amount of water in your body, or with diuretics which reduce the amount of sodium in your body)

If you are going to receive an anaesthetic. This may be given for an operation or any dental work. You may need to stop your TRITACE treatment one day beforehand; ask your doctor for advice before going to bed.

If you are taking medicines or have conditions which may increase the risk of angioedema, a serious allergic reaction, or medicines such as mTOR inhibitors (e.g. temsirolimus, everolimus, sirolimus), vildagliptin, neprilysin (NEP) inhibitors (such as sacubitril/valsartan) or saracibtril/valsartan. For sacubitril/valsartan, see section 2. Do not take TRITACE.

If you are taking any of the following medicines used to treat high blood pressure:
- an angiotensin II receptor blocker (ARBs) (also known as sarantril for example valsartan, telmisartan, olmesartan), in particular if you have diabetes-related kidney problems
- aliskiren
Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g., potassium) in your blood at regular intervals. See also information under the heading "Do not take TRITACE."

Children and adolescents
TRITACE is not recommended for use in children and adolescents below 18 years of age because of the safety and efficacy of TRITACE in children has not yet been established.

If any of the above apply to you (or you are not sure), talk to your doctor before taking TRITACE.

Other medicines and TRITACE
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because TRITACE may affect the way some other medicines work. Also some medicines can affect the way TRITACE works.

Tell your doctor if you are taking any of the following medicines. They may make TRITACE work less well or have side effects if you take them with TRITACE:

- • Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and aspirin)
- • Medicines used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies such as ophedrine, nonadrenaline or adrenaline.

Your doctor will need to check your blood pressure.

Tell your doctor if you are taking any of the following medicines. They can increase the chance of getting side effects if you take them with TRITACE:

- • Saruntil/vahiran – used for treating a type of long-term (chronic) heart failure in adults (see section 2 Do not take TRITACE)
- • Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and aspirin)
- • Medicines for cancer (chemotherapy)
- • Medicines to stop the rejection of organs after a transplant such as ciclosporin
- • Diuretics (water tablets) such as furosemide
- • Medicines which can increase the amount of potassium in your blood such as spironolactone, triamterene, amiloride, potassium salts, thiazide alone or in combination with sulphinpyrazone (for infections) and heparin (for circulatory problems and in heart failure)
- • Steroid medicines for inflammation such as prednisolone
- • Alopoenil (used to lower the uric acid in your blood)
- • Cordarone (for heart rhythm problems)
- • Temocillin (for cancer)
- • Sildenafil, everolimus, or belatacept (for prevention of graft rejection)
- • Vildagliptin (used for treating type 2 diabetes)
- • Rasacitabine (used against diarrhoea)
- • Your doctor may need to change your dose and/or to take other precautions if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the heading "Do not take TRITACE" and "WARNINGS and precautions")

Tell your doctor if you are taking any of the following medicines. They may be affected by TRITACE:

• Medicines for diabetes such as oral glucose lowering medicines and insulin. TRITACE may lower your blood sugar amounts. Check your blood sugar amounts closely while taking TRITACE
• Lithium (for mental health problems). TRITACE may increase the amount of lithium in your blood. Your lithium amount will need to be closely checked by your doctor.

If any of the above apply to you (or you are not sure), talk to your doctor before taking TRITACE.

How much to take

The usual dose is 10 mg daily. Two administrations per day are preferable.

TREATMENT of high blood pressure

• The usual starting dose is 1.25 mg or 2.5 mg once daily.
• Your doctor will adjust the amount you take.
• The usual dose is 5 mg or 10 mg once daily.

Treatment to reduce or delay the worsening of kidney problems

• You may be started on a dose of 1.25 mg or 2.5 mg once daily.
• Your doctor will adjust the amount you are taking.
• The usual dose is 5 mg or 10 mg once daily.

Treatment of heart failure

• The usual starting dose is 1.25 mg once daily.
• Your doctor will adjust the amount you take.
• The maximum dose is 10 mg daily. Two administrations per day are preferable.

If you take more TRITACE than you should tell a doctor or go to the hospital casualty department straight away. Do not drive to the hospital, get somebody else to take you or call for an ambulance. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you forget to take TRITACE

• If you miss a dose, take your normal dose when it is next due.
• Do not take a double dose to make up for a forgotten dose.

Driving and using machines

You may feel dizzy, while taking TRITACE. This is more likely to happen when you start taking TRITACE or start taking a higher dose. If this happens, do not drive or use any tools or machines.

Other side effects include:

• Skin rash with or without raised area
• Chest pain
• Cramps or pain in your muscles
• Blood tests showing more potassium than usual in your blood.

Uncommon (may affect up to 1 in 100 people)

• Balance problems (vertigo)
• itching and unusual skin sensations such as numbness, tingling, prickling, burning or creeping on your skin (paresthesia)
• Loss or change in the way things taste
• Sleep problems
• Feeling depressed, anxious, more nervous than usual or restless
• Blocked nose, difficulty breathing or worsening of asthma
• A swelling in your gut called "intestinal angioedema" presenting with symptoms like abdominal pain, vomiting and diarrhoea
• Heartburn, constipation or dry mouth
• Passing more water (urine) than usual over the day
• Sweating more than usual
• Renal (kidney) problems (may affect up to 1 in 100 people)
• Hair loss.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking TRITACE and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

• Swelling of the face, lips or throat which make it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to TRITACE
• Severe skin reactions including rash, ulcers in your mouth, worsening of a pre-existing skin disease, reddening, blistering or detachment of skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme).

Tell your doctor immediately if you experience:

Faster heart rate, unlovers or forceful heartbeat (palpitations), chest pain, tightness in your chest or more serious problems including heart attack and stroke
• Shortness of breath or a cough. These could be signs of lung problems
• Bruising more easily, bleeding for longer than normal, any sign of bleeding (e.g. bleeding from the gums), purple spots, blotching on the skin or getting infections more easily than usual, sore throat and fever, feeling tired, faint, dizzy or having pale skin. These can be signs of blood or bone marrow problems
• Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis (inflammation of the pancreas)
• Fever, chills, tenderness, loss of appetite, stomach pain, feeling sick, yellowing of your skin or eyes (jaundice). These can be signs of liver problems such as hepatitis (inflammation of the liver) or liver damage
• Fainting, hypotension (abnormally low blood pressure) especially when you stand or sit up quickly
• Dry looking cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath
• Stomach or gut pain, diarrhoea, indigestion, feeling or being sick

Taking this medicine

• Drinking alcohol with TRITACE may make you feel dizzy or light headed. If you are concerned about how much you can drink while you are taking TRITACE, discuss this with your doctor as medicines used to reduce blood pressure and alcohol can have additive effects.
• TRITACE may be taken with or without food.

Pregnancy and breast-feeding

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. They can make TRITACE work less well or have side effects if you take them with TRITACE:

• Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and aspirin)
• Medicines used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies such as ophedrine, nonadrenaline or adrenaline.

Your doctor will need to check your blood pressure.

Tell your doctor if you are taking any of the following medicines. They can increase the chance of getting side effects if you take them with TRITACE:

- • Saruntil/vahiran – used for treating a type of long-term (chronic) heart failure in adults (see section 2 Do not take TRITACE)
- • Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and aspirin)
- • Medicines for cancer (chemotherapy)
- • Medicines to stop the rejection of organs after a transplant such as ciclosporin
- • Diuretics (water tablets) such as furosemide
- • Medicines which can increase the amount of potassium in your blood such as spironolactone, triamterene, amiloride, potassium salts, thiazide alone or in combination with sulphinpyrazone (for infections) and heparin (for circulatory problems and in heart failure)
- • Steroid medicines for inflammation such as prednisolone
- • Alopoenil (used to lower the uric acid in your blood)
- • Cordarone (for heart rhythm problems)
- • Temocillin (for cancer)
- • Sildenafil, everolimus, or belatacept (for prevention of graft rejection)
- • Vildagliptin (used for treating type 2 diabetes)
- • Rasacitabine (used against diarrhoea)
- • Your doctor may need to change your dose and/or to take other precautions if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the heading "Do not take TRITACE" and "WARNINGS and precautions")

Tell your doctor if you are taking any of the following medicines. They may be affected by TRITACE:

• Medicines for diabetes such as oral glucose lowering medicines and insulin. TRITACE may lower your blood sugar amounts. Check your blood sugar amounts closely while taking TRITACE
• Lithium (for mental health problems). TRITACE may increase the amount of lithium in your blood. Your lithium amount will need to be closely checked by your doctor.

If any of the above apply to you (or you are not sure), talk to your doctor before taking TRITACE.