

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tritace[®] 5mg Tablets

Ramipril

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- 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.

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1. What TRITACE is and what it is used for
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1. What Tritace is and what it is used for?

TRITACE contains a medicine called ramipril. This belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme Inhibitors).

TRITACE works by:

- Decreasing your body's production of substances that could raise your blood pressure
- Making your blood vessels relax and widen
- Making it easier for your heart to pump blood around your body.

TRITACE can be used:

- To treat high blood pressure (hypertension)
- To reduce the risk of you having a heart attack or stroke
- To reduce the risk or delay the worsening of kidney problems (whether or not you have diabetes)
- To treat your heart when it cannot pump enough blood to the rest of your body (heart failure)
- As treatment following heart attack (myocardial infarction) complicated with heart failure.

2. Before you take Tritace

Do not take Tritace

- If you are allergic (hypersensitive) to ramipril, any other ACE inhibitor medicine or any of the ingredients of TRITACE listed in section 6.
- Signs of an allergic reaction may include a rash, swallowing 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 itching, hives (urticaria), 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 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)
- If you are more than 3 months pregnant. It is also better to avoid TRITACE in early pregnancy. (see section "Pregnancy and breast-feeding")
- If your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment.

Do not take TRITACE if any of the above apply to you. If you are not sure, talk to your doctor before taking TRITACE.

Take special care with Tritace

Check with your doctor or pharmacist before taking your medicine:

- 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 allergy to bee or wasp stings (desensitization)
- 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
- If you have high amounts of potassium in your blood (shown in blood test results)
- If you have collagen vascular disease such as scleroderma or systemic lupus erythematosus
- You must tell your doctor if you think that you are (or might become) pregnant. TRITACE 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 (see section "Pregnancy and breast-feeding").

Children

TRITACE is not recommended for use in children and adolescents below 18 years of age because 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.

Taking TRITACE with 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 (including herbal medicines). This is because TRITACE can affect the way some other medicines work. Also some medicines can affect the way TRITACE works.

Please tell your doctor if you are taking any of the following medicines. They can make TRITACE work less well:

- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indometacin and aspirin)
- Medicines used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies such as ephedrine, noradrenaline or adrenaline. Your doctor will need to check your blood pressure.

Please 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:

- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indometacin 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 and heparin (for thinning blood)
- Steroid medicines for inflammation such as prednisolone
- Allopurinol (used to lower the uric acid in your blood)
- Procainamide (for heart rhythm problems).

Please 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.

Taking TRITACE with food and alcohol

- 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

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Tritace before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Tritace. Tritace is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Tritace is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Ask your doctor or pharmacist for advice before taking any medicine.

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.

3. How to take Tritace?

Always take TRITACE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth at the same time of the day each day.
- Swallow the tablets whole with liquid.
- Do not crush or chew the tablets.

How much to take

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 until your blood pressure is controlled.
- The maximum dose is 10 mg once daily.
- If you are already taking diuretics (water tablets), your doctor may stop or reduce the amount of the diuretic you take before beginning treatment with TRITACE.

To reduce the risk of you having a heart attack or stroke

- The usual starting dose is 2.5 mg once daily.
- Your doctor may then decide to increase the amount you take.
- The usual dose is 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.

Treatment after you have had a heart attack

- The usual starting dose is 1.25 mg once daily to 2.5 mg twice daily.
- Your doctor will adjust the amount you take.
- The usual dose is 10 mg daily. Two administrations per day are preferable.

Elderly

Your doctor will reduce the initial dose and adjust your treatment more slowly.

If you take more TRITACE than you should

Tell a doctor or go to the nearest 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 tablet.

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

4. Possible side effects

Like all medicines, TRITACE 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 multiform).

Tell your doctor immediately if you experience:

- Faster heart rate, uneven 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, tiredness, 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.

Other side effects include:

Please tell your doctor if any of the following gets serious or lasts longer than a few days.

Common (affects less than 1 in 10 people)

- Headache or feeling tired
- Feeling dizzy. This is more likely to happen when you start taking TRITACE or start taking a higher dose
- Fainting, hypotension (abnormally low blood pressure), especially when you stand or sit up quickly
- Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath
- Stomach or gut pain, diarrhoea, indigestion, feeling or being sick
- 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 (affects less than 1 in 100 people)

- Balance problems (vertigo)
- Itching and unusual skin sensations such as numbness, tingling, pricking, burning or creeping on your skin (paraesthesia)
- 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
- Loss or decrease of appetite (anorexia)
- Increased or irregular heartbeats
- Swollen arms and legs. This may be a sign of your body holding onto more water than usual
- Flushing
- Blurred vision
- Pain in your joints
- Fever
- Sexual inability in men, reduced sexual desire in men or women
- An increased number of certain white blood cells (eosinophilia) found during a blood test
- Blood tests showing changes in the way your liver, pancreas or kidneys are working.

Rare (affects less than 1 in 1,000 people)

- Feeling shaky or confused
- Red and swollen tongue
- Severe flaking or peeling of the skin, itchy, lumpy rash
- Nail problem (e.g. loosening or separation of a nail from its bed)
- Skin rash or bruising
- Blotches on your skin and cold extremities
- Red, itchy, swollen or watery eyes
- Disturbed hearing and ringing in your ears
- Feeling weak
- Blood tests showing a decrease in the number of red blood cells, white blood cells or platelets or in the amount of haemoglobin.

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

- Being more sensitive to the sun than usual.

Other side effects reported:

Please tell your doctor if any of the following gets serious or lasts longer than a few days.

- Difficulty concentrating
- Swollen mouth
- Blood tests showing too few blood cells in your blood
- Blood tests showing less sodium than usual in your blood
- Fingers and toes changing colour when you are cold and then tingling or feeling painful when you warm up (Raynaud's phenomenon)
- Breast enlargement in men
- Slowed or impaired reactions
- Burning sensation
- Change in the way things smell
- Hair loss.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Tritace

- Keep out of the reach and sight of children.
- Do not use your tablets after the expiry date shown on the label and blister. The expiry date is embossed on the bottom of the reverse side of the blister strip and refers to the last day of that month.
- Store below 25°C
- Store in the original package.
- Medicines should not be disposed of via waste water or household waste.
- Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. Further Information

Tritace 5 mg tablets are red and contain 5 mg ramipril as their active ingredient.

Each tablet also contains hypromellose, pregelatinised maize starch, microcrystalline cellulose and sodium stearyl fumarate. and the colour red ferric oxide (E172).

Tritace is presented in a blister (calendar) pack of 28 tablets.

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Manufacturer:

Sanofi Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main, Germany or Sanofi Aventis S.p.A, Strada Statale 17 Km 22, 67019 Scoppito, Italy or Sanofi Winthrop Industrie 6, boulevard de l'Europe, 21800 Quetigny, France

REMEMBER this medicine is for YOU. Only a doctor can prescribe it for you. Never give it to other people. It may harm them, even if they have the same symptoms as you.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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