

TRITACE® 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

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1. WHAT IS TRITACE USED FOR

Tritace is used

- to treat high blood pressure (hypertension)
- to treat your heart when it cannot pump enough blood to the rest of your body (congestive heart failure)
- as treatment following heart attack (myocardial infarction) complicated with heart failure
- to reduce the risk of you having a heart attack or stroke
- for prevention of worsening of kidney problems in patients with persistent proteinuria (presence of excess protein in urine).

2. HOW TRITACE WORKS

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

3. BEFORE YOU TAKE TRITACE

When you must not take it

- If you are allergic (hypersensitive) to ramipril, any other ACE inhibitor medicine or any of the other ingredients of Tritace. 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 kidneys is reduced (renal artery stenosis)
- During the last **6 months of pregnancy** (2nd or 3rd trimester) (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 are diabetes mellitus or have renal impairment (GFR < 60 ml/min/1.73m²) and are taking aliskiren-containing products.

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

Before you start to take it

Check with your doctor or pharmacist before taking your medicine:

- If you have heart, liver or kidney problems
- If you are at particular risk of low blood pressure (hypotension)
- If you are going to have treatment to reduce your allergy to bee or wasp stings (desensitization)
- If you are going to have a surgery, you may need to stop your Tritace treatment one day beforehand
- If you have high amounts of potassium in your blood (shown in blood test results)
- You must tell your doctor if you think that you are (or might become) pregnant. Tritace is not recommended in the first 3 months of pregnancy and may cause serious harm to your baby after 3 months of pregnancy, see section *Pregnancy and breast-feeding*.
- Monitor kidney function before and during treatment

Children

Tritace is not recommended for use in children and adolescents below 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 (including herbal medicines).

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 indomethacin and aspirin)

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- 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 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 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 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.

- mTOR inhibitors (anticancer drug) or DPP –IV inhibitors (oral anti-diabetic drug) increases risk of severe swelling beneath the skin.
- If you take ACE inhibitors together with NEP inhibitors (like racecadotril), there is a higher chance you could develop angioedema.
- The concomitant use of ACE inhibitors with sacubitril/valsartan is contraindicated as this increases the risk of angioedema.

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.

4. HOW TO TAKE TRITACE

How much to take

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

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

- The usual starting dose is 1.25 mg once daily.
- Your doctor will adjust the amount you are taking.

Treatment of heart failure

- The usual starting dose is 1.25 mg once daily.
- Your doctor will adjust your dose
- The maximum dose is 10 mg daily.

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 maximum dose is 10 mg daily.

Elderly

The recommended starting dose is 1.25 mg once daily, which can then be increased according to the individual patient's blood pressure response.

Please see Package Insert for detailed dosage information.

When to take it

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 long to take it

Therapy with Tritace is usually long-term therapy; the doctor determines the duration of treatment individually for each patient. Do not stop taking

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Tritace unless instructed by your doctor.

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/capsule.

If you take too much (overdose)

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

5. WHILE YOU ARE USING TRITACE

Things you must do

Take Tritace according to your doctor's instructions.

Tell your doctor or pharmacist if any side effect become serious, or if you notice any side effects not listed in this leaflet.

Things you must not do

Do not stop taking Tritace unless advised by your doctor.

Things to be careful of

Pregnancy and breast-feeding

You must tell your doctor if you think that you are (or might become) pregnant.

Tritace is not recommended during the first trimester of pregnancy and contraindicated during the second and third trimesters of pregnancy (see section *When you must not take it*) as its use during pregnancy may possibly be harmful to the baby.

If you become pregnant while on Tritace, tell your doctor immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

You should not take Tritace if you are breast-feeding.

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 machines.

6. SIDE EFFECTS

Like all medicines, Tritace 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 makes 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 or liver damage.

A list of possible side effects is given below.

Very common: affects more than 1 in 10 patients

Common: affects more than 1 in 100 but less than 1 in 10 patients

Uncommon: affects more than 1 in 1,000 but less than 1 in 100 patients

Rare: affects more than 1 in 10,000 but less than 1 in 1,000 patients

Very rare: affects less than 1 in 10,000 patients

Common

- Headache, dizziness, feeling tired
- Fainting, low blood pressure (hypotension), especially when you stand or sit up quickly
- Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath
- Stomach discomfort, diarrhoea, indigestion, nausea, vomiting
- Skin rash with or without raised area
- Chest pain
- Muscle cramps or pain
- Blood potassium increased

Uncommon

- Balance problems (vertigo)
- Itching and unusual skin sensations such as numbness, tingling, pricking or burning on your skin (paraesthesia)
- Loss or change in the way things taste
- Sleep problems

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- 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
- Loss or decrease of appetite (anorexia)
- Increased or irregular heart beats
- Angioedema
- Blurred vision
- Pain in your joints
- Fever
- Impotence; 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

- Feeling shaky, balance disorder, confusion
- Red and swollen tongue
- Severe flaking or peeling skin, itchy, lumpy rash
- Nail problems (e.g. loosening or separation of a nail from its bed)
- Damage of liver cells, cholestatic jaundice
- Narrowing of blood vessel (vascular stenosis), decreased blood flow through an organ (hypoperfusion), inflammation of a blood vessel (vasculitis)
- Red, itchy, swollen or watery eyes
- Disturbed hearing or 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

- 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.

7. STORAGE AND DISPOSAL OF TRITACE

Keep out of the reach and sight of children.

Store below 30°C.

Do not use Tritace after the expiry date.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. PRODUCT DESCRIPTION

What it looks like

Tritace 2.5 mg Tablet: Yellowish to yellow oblong tablets with score-line, Upper stamp: 2.5 and company logo, Lower stamp: HMR and 2.5

Tritace 5 mg Tablet: pale red oblong tablets with score-line,

Upper stamp: 5 and company logo, Lower stamp: HMP and 5

Tritace 10 mg Tablet: White to almost white oblong tablets with score-line,

Upper stamp: HMO/HMO, Lower stamp: anonymous

Ingredients

Active substance

Tritace 2.5 mg Tablet: One tablet contains 2.5 mg ramipril.

Tritace 5 mg Tablet: One tablet contains 5 mg ramipril.

Tritace 10 mg Tablet: One tablet contains 10 mg ramipril.

Other ingredients

Hypromellose, pregelatinized starch (maize starch), microcrystalline cellulose and sodium stearyl fumarate, yellow ferric oxide (E 172, only in Tritace 2.5 mg tablets), red ferric oxide (E 172, only in Tritace 5 mg tablets).

MAL NO.

Tritace 2.5 mg Tablet:
MAL19986949AZ

Tritace 5 mg Tablet:
MAL19986948AZ

Tritace 10 mg Tablet:
MAL20031929AZ

MANUFACTURER

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TRITACE® TABLETS

Ramipril

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