Tablets 5 mg
Pale red oblong tablet of 8x4mm with score line, upper stamp 5 and company logo, lower stamp HMP and 5. The tablet can be divided into equal doses.

Tablets 10 mg
White to almost white oblong tablet of 7x4.5mm with score line, upper stamp HMO/HMO. The tablet can be divided into equal doses.

TRITACE 1.25 mg tablets are supplied in packs of 14, 15, 20, 28, 30, 50, 90, 98, 100 tablets in PVC/Alu blisters and in packs of 500 tablets in brown glass bottle with cap.

TRITACE 2.5 mg tablets are supplied in packs of 7, 10, 14, 15, 18, 20, 28, 30, 45, 50, 60, 90, 98, 99, 100, 300, 320, 500 tablets in PVC/Alu blisters and in packs of 500 tablets in brown glass bottle with cap.

TRITACE 5 mg tablets are supplied in packs of 10, 14, 15, 18, 20, 21, 28, 30, 45, 50, 56, 90, 98, 99, 100, 300, 320, 500 tablets in PVC/Alu blisters and in packs of 500 tablets in brown glass bottle with cap.

TRITACE 10 mg tablets are supplied in packs of 7, 10, 14, 15, 18, 20, 28, 30, 45, 50, 56, 90, 98, 99, 100, 300, 320, 500 tablets in PVC/Alu blisters and in packs of 28, 56, 500 tablets in brown glass bottle with cap.
Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
sanofi-aventis Ireland Ltd. T/A SANOFI
Citywest Business Campus,
Dublin 24,
Ireland
Tel: 01 4035600
email: IEmedinfo@sanofi.com

808089 - 89036473 4/4

Manufacturer
Manufacturer - for Tritace 1.25mg, 2.5mg, 5mg and 10mg tablets:
Sanofi S.r.l.
Strada Statale 17km: 22
67019 Scoppito (AQ)
Italy

OR

S.C. ZENTIVA S.A.,
B-dul Theodor Pallady nr. 50,
Sector 3, Bucuresti,
032266 Romania

Manufacturer - for Tritace 2.5mg, 5mg and 10mg tablets:
Delpharm Dijon
6, Boulevard de l'Europe
21800 Quetigny
FRANCE

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:
Tritace 1.25 mg Tabletten, Tritace 2.5 mg Tabletten, Tritace 5 mg Tabletten, Tritace 10 mg Tabletten

Belgium:
Tritace 2.5 mg tabletten/comprimés/Tabletten, Tritace 5 mg tabletten/comprimés/Tabletten, Tritace 10 mg tabletten/comprimés/Tabletten

Bulgaria:
Tritace 5 mg таблетки, Tritace 10 mg таблетки

Cyprus:
Triatec 2.5 mg δισκία, Triatec 5 mg δισκία

Czech Republic:
Tritace 1.25 mg tablety, Tritace 2.5 mg tablety, Tritace 5 mg tablety, Tritace 10 mg tablety

Denmark:
Triatec 5 mg tabletter

Estonia:
Cardace 2.5 mg tabletid, Cardace 5 mg tabletid, Cardace 10 mg tabletid

Finland:
Cardace 2.5 mg tabletit, Cardace 5 mg tabletit, Cardace 10 mg tabletit

France:
Triatec 1.25 mg comprimé, Triatec 2.5 mg comprimé sécable, Triatec 5 mg comprimé sécable, Triatec 10 mg comprimé sécable

Germany:
Delix 2.5 mg Tabletten, Delix 5 mg Tabletten, Delix Protect 10 mg Tabletten
Delix Protect Startset
Delix 1.25 mg Tabletten,
Delix 1.25 mg Kapseln, Delix P 2.5 mg Kapseln, Delix P 5 mg Kapseln, Delix P 10 mg Kapseln

Greece:
Triatec 2.5 mg δισκία, Triatec 5 mg δισκία

Hungary:
Tritace Mite 1.25 mg tabletta
Tritace 2.5 mg tabletta, Tritace 5 mg tabletta, Tritace 10 mg tabletta

Ireland:
Tritace 1.25 mg tabs, Tritace 2.5 mg tabs, Tritace 5 mg tabs, Tritace 10 mg tabs

Italy:
Triatec 2.5 mg compresse, Triatec 5 mg compresse, Triatec 10 mg compresse

Latvia:
Cardace 2.5 mg tabletes, Cardace 5 mg tabletes, Cardace 10 mg tabletes

Lithuania:
Cardace 5 mg tabletės,
Cardace 10 mg tabletės

Luxembourg:
Tritace 2.5 mg tabletten/comprimés/Tabletten, Tritace 5 mg tabletten/comprimés/Tabletten, Tritace 10 mg tabletten/comprimés/Tabletten

Norway:
Triatec 2.5 mg tabletter, Triatec 5 mg tabletter, Triatec 10 mg tabletter

Poland:
Tritace 2.5 mg tabletki, Tritace 5 mg tabletki, Tritace 10 mg tabletki

Portugal:
Triatec 1.25 mg cápsulas, Triatec 2.5 mg cápsulas, Triatec 5 mg cápsulas, Triatec 10 mg cápsulas

Romania:
Tritace 2.5 mg comprimate, Tritace 5 mg comprimate, Tritace 10 mg comprimate

Slovak Republic:
Tritace 1.25 mg tablety, Tritace 2.5 mg tablety, Tritace 5 mg tablety, Tritace 10 mg tablety

Slovenia:
Tritace 1.25 mg tablete, Tritace 2.5 mg tablete, Tritace 5 mg tablete, Tritace 10 mg tablete

Spain:
Acovil 2.5 mg comprimidos, Acovil 5 mg comprimidos, Acovil 10 mg comprimidos

Sweden:
Triatec 2.5 mg tabletter, Triatec 5 mg tabletter, Triatec 10 mg tabletter

United Kingdom:
Tritace 1.25 mg tablets, Tritace 2.5 mg tablets, Tritace 5 mg tablets, Tritace 10 mg tablets, Tritace Titration Pack tablets

This leaflet was last approved in February 2021.

Package leaflet: Information for the user

Tritace® 1.25mg Tablets
Tritace® 2.5mg Tablets
Tritace® 5mg Tablets
Tritace® 10mg Tablets

Ramipril

SANOFI

Is this leaflet hard to see or read? Phone 01 4035600 for help.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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. What you need to know before you take TRITACE

Do not take TRITACE:
- 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, 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 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 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)
- You are taking medicines or have conditions which may decrease sodium levels in your blood. Your doctor may carry out regular blood tests, particularly for checking the levels of sodium in your blood especially if you are elderly.
- If you are taking medicines that may increase the risk of angioedema, a serious allergic reaction, such as mTOR inhibitors (e.g. temsirolimus, everolimus, sirolimus), vildagliptin, neprilysin (NEP) inhibitors (such as racecadotril) or sacubitril/valsartan. For sacubitril/valsartan, see section 2 'Do not take Tritace'.
- 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 the first 3 months of pregnancy and may cause serious harm to your baby after 3 months of pregnancy (see section below on "Pregnancy and breast-feeding").
- If you are taking any of the following medicines used to treat high blood pressure:
  - an angiotensin II receptor blocker (ARBs) (also known as sartans-for example valsartan, telmisartan, irbesartan), 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".

Turn Over

808089 - 89036473 1/4

DATE: 02-03-2021
DESCRIPTION: IST TRITACE IE I02
PACK. ITEM: Istruzioni
MARKET: IE: IRELAND
COLOURS: ■ Reflex Blue
CODE SAP/ID N°: 808089 89036473
REPLACED CODE SAP/ID N°: 800127 89036295
TECHNICAL DRAW. CODE: 62C0007 V.1.0
LAETUS: 1101111101
EXT. DIM.: 167 x 315mm DP
BLISTER SIZE:
PROOF N°: 1
PACKAGING LINE: -
DIE CUT: -
MIN. FONT SIZE: 9 pt su 9,5 pt
PAGE: 4, 1 / 4
BRAILLE: Fustella num.
IMPIANTO DI PROPRIETÀ: Sanofi S.p.A.
Arkhè S.n.c.
Tel. 0862.404140
fax 0862.090006
Verificare la corrispondenza dell'artwork approvato - la nostra responsabilità è limitata al rifacimento dei file forniti.
Text approval Date: Signature:
Final approval Date: Signature:
1 - Prima realizzazione

Children and adolescents
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.

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 can 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 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.

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:
- Sacubitril/valsartan – 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 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, trimethoprim alone or in combination with sulfamethoxazole (for infections) 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)
- Temsirolimus (for cancer)
- Sirolimus, everolimus (for prevention of graft rejection)
- Vildagliptin (used for treating type 2 diabetes)
- Racecadotril - 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 headings "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.

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 that you are (or might become) pregnant.
You should not take TRITACE in the first 12 weeks of pregnancy and you must not take them at all from the 13th week as their 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.

Breast-feeding
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 tools or machines.

TRITACE contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take TRITACE

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

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.

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.

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

Common (may affect up to 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 (may affect up to 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 (may affect up to 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 (may affect up to 1 in 10,000 people)
- Being more sensitive to the sun than usual.

Other side effects reported:
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
- Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion. If you have these symptoms contact your doctor as soon as possible
- 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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TRITACE

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the cartons, blisters and bottles after EXP. The expiry date refers to the last day of that month. This medicine does not require any special storage conditions.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What TRITACE contains

The active substance is ramipril.

1.25 mg: Each tablet contains ramipril 1.25 mg
2.5 mg: Each tablet contains ramipril 2.5 mg
5 mg: Each tablet contains ramipril 5 mg
10 mg: Each tablet contains ramipril 10 mg

The other ingredients in the tablets are:

Tablets 1.25 mg and 10 mg
Hypromellose
Pregelatinized maize starch
Microcrystalline cellulose
Sodium stearylfumarate

Tablets 2.5 mg
Hypromellose
Pregelatinized maize starch
Microcrystalline cellulose
Sodium stearylfumarate
Yellow ferric oxide (E172)

Tablets 5 mg
Hypromellose
Pregelatinized maize starch
Microcrystalline cellulose
Sodium stearylfumarate
Red ferric oxide (E172)

What TRITACE looks like and contents of the pack
Tablets 1.25 mg
White to almost white oblong tablet of 8x4mm with score line, upper stamp 1.25 and company logo, lower stamp HMN and 1.25. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Tablets 2.5 mg
Yellowish to yellow oblong tablet of 8x4mm with score line, upper stamp 2.5 and company logo, lower stamp HMR and 2.5. The tablet can be divided into equal doses.

Turn Over

DATE: 02-03-2021
DESCRIPTION: 1ST TRITACE IE I02
PACK. ITEM: Istruzioni
MARKET: IE: IRELAND
LAETUS: 110111101
COLOURS: ■ Reflex Blue
CODE SAP/ID N°: 808089 89036473
REPLACED CODE SAP/ID N°: 800127 89036295
TECHNICAL DRAW. CODE: 62C0007 V.1.0
EXT. DIM.: 167 x 315mm DP
DIE CUT: -
PROOF N°.: 1
BUSTER SIZE:
BRAILLE: fustella num.
PACKAGING LINE: -
MIN. FONT SIZE: 9 pt su 9,5 pt
PAGE: 2, 3 / 4
PRODUCT LOGO:
IMPIANTO DI PROPRIETÀ: Sanofi S.p.A.
Arkhé S.n.c.
Tel. 0862.404140
fax 0862.090006
Verificare la corrispondenza dell'artwork approvato - la nostra responsabilità è limitata al rifacimento dei file forniti.
Text approval Date: Signature:
Final approval Date: Signature:
1 - Prima realizzazione