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 carton and blister pack 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 sewage 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.
- The other ingredients are Hypromellose, pregelatinised maize starch, microcrystalline cellulose, sodium stearyl fumarate.
- The 2.5 mg tablets also contain yellow ferric oxide (E172).
- The 5 mg tablets also contain red ferric oxide (E172).

What TRITACE looks like and contents of the pack
- TRITACE® 12.5 mg Tablets are white to almost white oblong tablets with score-line. The upper face is marked with 1.25 and a logo (S) and the lower face is marked with HMR and 2.5. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
- TRITACE® 2.5 mg Tablets are yellowish to yellow oblong tablets with a score-line. The upper face is marked with 2.5 and a logo (S) and the lower face is marked with HMR and 2.3. The tablet can be divided into equal halves.
- TRITACE® 5 mg Tablets are pale red oblong tablets with a score-line. The upper face is marked with 5 and a logo (S) and the lower face is marked with HMR and 2.5. The tablet can be divided into equal halves.
- TRITACE® 10 mg Tablets are white to almost white oblong tablets with a score-line. The upper face is marked with HMO/HMO and the lower face is unmarked. The tablet can be divided into equal halves.
- All strengths are supplied in PVC/aluminium blisters in packs of 28 tablets.

Your Tritace Tablets Titration Pack contains 3 different strengths of Tritace Tablets in 3 different cartons.
- 10 x 2.5 mg ramipril/ yellowish to yellow oblong tablets with a score-line. The upper face is marked with 2.5 and a logo (S) and the lower face is marked with HMR and 2.5.
- 30 x 5 mg ramipril/ pale red oblong tablets with a score-line. The upper face is marked with 5 and a logo (S) and the lower face is marked with HMR and 5.
- 10 x 10 mg ramipril/ white to almost white oblong tablets with a score-line. The upper face is marked with HMO/HMO and the lower face is unmarked.

Your Titration Pack is available in packs containing a total of 50 tablets.
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 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 indomethacin and aspirin)
- Medicines used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies such as ophendrine, 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 – you may need urgent medical treatment:

- Biologics (e.g. monoclonal antibodies)
- Medicines used to stop the rejection of organs after a transplant (e.g. tacrolimus, cyclosporine, sirolimus, everolimus)
- Medicines used to relieve pain and inflammation which can increase the amount of potassium in your blood, such as indomethacin, ibuprofen, ibuprofen and naproxen.
- Medicines which can increase the amount of sodium in your blood, such as ephedrine, noradrenaline or adrenaline.
- 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 (e.g. cyclosporin)
- 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 sulphonamides (for infections) and heparin (for thinning blood)
- Steroid medicines for inflammation as well as long-term diabetes.
- Alopurinol (used to lower the uric acid in your blood)
- Oxybutynin (for chronic bladder pain)
- Temazepam (for heart rhythm problems)
- Vildagliptin (used for treating type 2 diabetes)
- Ramipril (used against diabetics)
- 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 affect the way TRITACE works:

- Medicines for diabetes such as oral glucose lowering medicines and insulins. 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.

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 usual 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 and increase 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.

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.

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/capsules whole with liquid.

Do not crush or chew the tablets/capsules.

If you take more TRITACE than you should

Tell a doctor or your 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.

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, unsteady or forceful heartbeat (palpitations), chest pain, tightness in your chest or more serious problems including heart attack and stroke.
- Nausea, vomiting or feeling sick.
- Shortness of breath or a cough. These could be signs of lung problems.
- Bruising more easily, bleeding for longer than normal, any signs of bleeding (e.g. bleeding from the gums), purple spots, blistering 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.

Yours are very rare (may affect 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.

- Difficult 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.
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 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:

- Medicines used to relieve pain and inflammation (e.g. Non-Steroideal 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 ophedrine, nonadrenaline or adrenaline.
- Other 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, triethopimolone alone or in combination with sulfamethoizole (for infections) and heparin (for treatment of blood clots)
- Steroid medicines for inflammation such as cortisone.
- Allergen (used to lower the uric acid in your blood)
- Angiotensin II receptor blockers (ARB) or aliskiren
- Sirolimus, everolimus (for prevention of graft rejection)
- Nesiritide (for heart rhythm problems)
- Temsirolimus (for cancer)
- Sildenafil, everolimus (for prevention of graft rejection)
- Vildagliptin (used for treating type 2 diabetes)
- Raltegravir (used against diarrhoea)

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

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 in reducing 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.

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 may then decide to increase the amount you take.

The usual dose is 10 mg once daily. This can be increased to 20 mg or 50 mg once daily.

Treatment to reduce or delay the worsening of kidney failure

- 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.

If you are also 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.

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/capsules whole with liquid. Do not crush or chew the tablets/capsules.

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 dose.

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 rash. 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, uncontrolled heartbeat (palpitations), chest pain, tightness in your chest or more problems including serious 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). There can be signs of liver problems such as hepatitis (inflammation of the liver) or liver damage.

- Numbness, tingling, pricking, 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.

- Easy or decrease of appetite (anorexia).

- Increased or irregular heartbeats.

- Swollen arms and legs. This may be a sign of your body holding on more water than usual.

- Feeling shaky or confused.

- Dizziness or light-headed. If you are concerned about this, ask your doctor.

- Feeling or being sick.

- Hair loss.

- 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 (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.

- Easy or decrease of appetite (anorexia).

- Increased or irregular heartbeats.

- Swollen arms and legs. This may be a sign of your body holding on more water than usual.

- Feeling shaky or confused.

- Dizziness or light-headed. If you are concerned about this, ask your doctor.

- Feeling or being sick.

- Hair loss.

- 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.

Rare (may affect up to 1 in 1,000 people)

- Feeling shaky or blurred.

- Red and swollen tongue.

- Severe flaking or peeling of the skin, itchy, lumpy rash.

- Nail problems (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 low 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 then tingling or feeling painful when you are warm (Raynaud’s phenomenon).

- Breast enlargement in men.

- Slowed or impaired reactions.

- Burning sensation.

- Change in the way things smell.

- Hair loss.

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 low 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 then tingling or feeling painful when you are warm (Raynaud’s phenomenon).

- Breast enlargement in men.

- Slowed or impaired reactions.

- Burning sensation.

- Change in the way things smell.

- Hair loss.
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 carton and blister pack 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.
- The other ingredients are Hypromellose, pregelatinised maize starch, microcrystalline cellulose, sodium stearyl fumarate.
- The 2.5mg tablets also contain yellow ferric oxide (E172).
- The 5mg tablets also contain red ferric oxide (E172).

What TRITACE looks like and contains of the pack

- TRITACE 1.25mg Tablets are white to almost white oblong tablets with score-line. The upper face is marked with 1.25 and a logo (©) and the lower face is marked with HM and 1.25. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
- TRITACE 2.5mg Tablets are yellowish to yellow oblong tablets with a score-line. The upper face is marked with 2.5 and a logo (©) and the lower face is marked with HM and 2.5. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
- TRITACE 5mg Tablets are pale red oblong tablets with a score-line. The upper face is marked with 5 and a logo (©) and the lower face is marked with HM and 5. The tablet can be divided into equal halves.
- TRITACE 10mg Tablets are white to almost white oblong tablets with a score-line. The upper face is marked with HM/HMO and the lower face is unmarked. The tablet can be divided into equal halves.

All strengths are supplied in PVC/aluminium blisters in packs of 28 tablets.

Your Tritace Tablets Titration Pack contains 3 different strengths of Tritace Tablets in 3 different cartons.
- 10 x 2.5mg ramipril (yellowish) to yellow oblong tablets with a score-line. The upper face is marked with 2.5 and a logo (©) and the lower face is marked with HM and 2.5.
- 30 x 5mg ramipril (pale red oblong tablets with a score-line. The upper face is marked with 5 and a logo (©) and the lower face is marked with HM and 5.
- 10 x 10mg ramipril (white) to almost white oblong tablets with a score-line. The upper face is marked with HM/HMO and the lower face is unmarked.

Your Titration Pack is available in packs containing a total of 50 tablets.