

Trinomia

Acetylsalicylic acid/atorvastatin /ramipril

100 mg/20 mg/10 mg hard capsules

100 mg/20 mg/5 mg hard capsules

100 mg/20 mg/2.5 mg hard capsules

WHAT IS IN THIS LEAFLET

Please read this leaflet carefully before you start using Trinomia.

This leaflet answers some common questions about Trinomia. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your pharmacist or doctor will be able to advise you about the risks and benefits of using Trinomia.

If you have any concerns about using this medicine, ask your pharmacist or doctor. Keep this leaflet with the medicine. You may need to read it again.

WHAT IS TRINOMIA USED FOR

Trinomia capsules contain three substances called acetylsalicylic acid, atorvastatin and ramipril.

- Acetylsalicylic acid belongs to a group of substances called antiplatelet agents that help prevent your blood cells sticking together and forming a blood clot.
- Atorvastatin belongs to a group of substances called statins, which are lipid (fat) regulating medicines that are used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, atorvastatin can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.
- Ramipril belongs to a group of substances called ACE inhibitors (Angiotensin Converting Enzyme Inhibitors) that works by decreasing your body's production of substances that could raise your blood pressure; making your blood vessels relax and widen and making it easier for your heart to pump blood around your body.

Trinomia is used as substitution therapy in adult patients adequately controlled with the three substances (acetylsalicylic acid, atorvastatin and ramipril) taken at the

same time at equivalent doses, to minimise the risk of having a cardiovascular accident, in patients who have already suffered a previous cardiovascular event.

Ask your doctor if you have any questions about why Trinomia has been prescribed for you.

BEFORE YOU USE TRINOMIA

When you must not use Trinomia

Do not use Trinomia:

- if you are allergic to acetylsalicylic acid , to other salicylates or to tartrazine (colouring agent). Signs of an allergic reaction may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you are allergic to ramipril or to any other ACE inhibitor medicine
- if you are allergic to atorvastatin , to any similar medicines used to lower blood lipids or to any of the other ingredients of the medicine (listed in Inactive Ingredients).
- if you are allergic to soya or peanut.
- if you have had asthma attacks or other hypersensitive reactions to certain medicines for pain, fever or inflammation (salicylates or other non-steroid anti-inflammatory drugs) in the past.
- if you have active, or history of recurrent peptic ulcer and/or gastric/intestinal haemorrhage, or other kinds of bleeding such as cerebrovascular haemorrhages if you have a high risk of bleeding (haemophilia).
- if you have heart disease that is not sufficiently controlled (severe heart failure).
- if you take 15 mg or more of methotrexate per week.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you have nasal polyps (inflamed swellings inside the nose) associated with asthma.
- if you have severe liver or kidney disease.
- if you have had any unexplained abnormal blood tests for liver function.
- if you are a woman able to have children and not using reliable contraception.
- if you are pregnant or trying to become pregnant.
- if you are breast-feeding.
- if you are taking:
 - HIV protease inhibitors such as tipranavir or ritonavir (medicines

used in the treatment of HIV).

- ciclosporin (a medicine often used in organ transplant patients).
- 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, Trinomia may not be suitable for you.
- if you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis).
- if your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment.
- if you are under 18 years of age. In case of children under 16 years with fever, flu or chicken pox exist risk of Reye syndrome.

Do not take Trinomia if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Trinomia.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist.

Before you start to use Trinomia

Talk to your doctor or pharmacist before taking Trinomia:

- if you are allergic to other pain medicines or anti-inflammatory drugs, other medicines for fever, rheumatism other than acetylsalicylic acid or to other substances that cause allergies.
- if you have other allergies (for example skin reactions, itching, hives).
- if you have bronchial asthma, hay fever, swelling of the nasal mucous membranes or chronic lung diseases.
- before operations or small interventions such as tooth extraction, because there may be a greater tendency for bleeding. You may need to stop taking Trinomia for a short time.
- if you have had stomach or intestinal ulcers or bleeding in the past.
- if you are taking simultaneous treatment with medicines to prevent blood clotting, medicines for pain, fever or inflammation (non-steroid anti-inflammatory drugs e.g. ibuprofen), corticosteroids (used to treat allergy or inflammation), antidepressants e.g. Selective Serotonin Re-uptake Inhibitors (SSRIs).
- 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 Trinomia”.
- if you have heart, liver or kidney problems. Trinomia may not be right for you.
- if you have a lack of glucose 6-phosphate dehydrogenase.
- if you are at risk for gout, because acetylsalicylic acid may reduce the excretion of uric acid. Under certain circumstances, this may cause an attack of gout.
- your doctor should do a blood test before you start taking Trinomia and regularly during the treatment. This is to check how well your liver is working.
- if you drink large amounts of alcohol.
- if you have severe respiratory failure.
- 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 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 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.

If the above applies to you talk to your doctor or pharmacist before taking Trinomia. Check with your doctor or pharmacist if you are not sure.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

The risk of muscle breakdown is greater in certain patients. Tell your doctor if any of the following applies to you:

- you have kidney problems.
- you have thyroid problems.
- you have ever had muscle problems during treatment with other lipid-lowering medicines (e.g. other ‘-statin’ or ‘-fibrate’ medicines).
- you or close family members have a hereditary muscle disorder.

- you consume large amounts of alcohol.
- you are more than 70 years old.

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g rhabdomyolysis is known to increase when certain medicines are taken at the same time (see “Taking other medicines”).

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Generally, it is recommended to correct dehydration, hypovolaemia or salt depletion before initiating treatment (in patients with heart failure, however, such corrective action must be carefully weighed out against the risk of volume overload).

If you require further advice, you should talk with your doctor or pharmacist.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. This is because Trinomia can affect the way some other medicines work. Also some other medicines can affect the way Trinomia works.

Trinomia contains acetylsalicylic acid and this substance can affect the way some other medicines work. Also some medicines can affect the way acetylsalicylic acid works. Please tell your doctor if you are taking any of the following medicines that may increase the chance of getting side effects:

- Anticoagulation medicines (for example coumarin and heparin) and medicines that dissolve blood clots may increase the risk of bleeding. Pay careful attention to signs of inner and outer bleeding (for example bruises) before treatment with these medicines.
- Other inhibitors of platelet aggregation (medicines that inhibit the cohesion or sticking of blood platelets) like ticlopidin and clopidogrel may increase the risk of bleeding.
- Medicines that contain cortisone or substances equivalent to cortisone such as prednisolone (with the exception of products that are applied on the skin or in cortisone therapy for Addison’s disease) increase the risk of undesirable effects in the gastrointestinal tract.
- Patients taking concomitant ACE inhibitor and DPP-IV inhibitor (eg, vildagliptin) or mTOR inhibitor (eg, everolimus, sirolimus) therapy may be at increased risk for angioedema. Caution should be used when starting a DPP-IV inhibitor or mTOR inhibitor in a patient already taking an ACE inhibitor.
- Other medicines for pain or inflammation (non-steroid analgesics such as ibuprofen or indometacin) and other rheumatism medicines in general increase the risk of bleeding and gastrointestinal ulcers.

- Medicines to reduce the blood glucose level (antidiabetic drugs) may cause low blood glucose levels.
- Digoxin (medicine to strengthen the heart).
- Methotrexate (treatment of cancer and certain rheumatic diseases).
- Valproic acid for treatment of convulsions attacks (epilepsy).
- Selective serotonin reuptake inhibitors (for treatment of depressions) may increase the risk of bleeding in the gastrointestinal tract.
- Ciclosporin (a medicine often used in organ transplant patients).
- Vancomycin (a type of antibiotic) can cause hearing problems.

Please tell your doctor if you are taking any of the following medicines that can make acetylsalicylic acid work less well:

- Particular medicines that result in an increased excretion of urine (diuretics, aldosterone antagonists like spironolactone and canrenoate, loop diuretics like furosemide).
- Medicines which promote the excretion of uric acid (for example probenecid and benzbromarone).

Please tell your doctor if you are taking any of the following medicines. They may be affected by acetylsalicylic acid:

- Ibuprofen: acetylsalicylic acid may reduce the effect of ibuprofen.
- Interferon α : acetylsalicylic acid reduce the activity of interferon α .
- Medicines to treat manic-depressive illness (lithium).
- Antiacids (used to treat indigestion).
- Barbiturates (used in the treatment of seizure disorders).
- Zidovudine (used in the treatment of HIV).
- Phenytoin (a medicine used to treat epilepsy).
- Acetylsalicylic acid may alter blood and urine tests.

Trinomia contains atorvastatin and this substance can also affect the way some other medicines work. Also some medicines can affect the way atorvastatin works. Alternatively it could increase the risk or severity of side-effects, including the important muscle wasting condition described in the above section "Before you start to use it"). Please tell your doctor if you are taking any of the following medicines:

- Ciclosporin (a medicine often used in organ transplant patients).
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampin, fusidic acid.
- Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, saquinavir, efavirenz, etc.
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol
- Some medicines used in the treatment of hepatitis C e.g. telaprevir

- Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem; medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone.
- Other medicines known to interact with atorvastatin include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives, stiripentol (an anti-convulsant for epilepsy), phenazone (a painkiller), cimetidine (an H2-receptor antagonists), colchicine (used to treat gout) and antacids (indigestion products containing aluminium or magnesium).
- Medicines obtained without a prescription: St John's Wort

Trinomia contains ramipril and this substance can also affect the way some other medicines work. Also some medicines can affect the way ramipril works. Please tell your doctor if you are taking any of the following medicines that may increase the chance of getting side effects:

- Medicines for cancer (chemotherapy).
- Medicines to stop the rejection of organs after a transplant such as ciclosporin.
- Diuretics 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 that can make Ramipril work less well:

- 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 may be affected by ramipril:

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

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 "When you must not use Trinomia" and

“Before you start to use Trinomia”.

If any of the above apply to you talk to your doctor or pharmacist before taking Trinomia. Check with your doctor or pharmacist if you are not sure.

You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/ her before you start using Trinomia.

Trinomia with food, drink and alcohol

Alcohol increases the risk of stomach and intestinal ulcers and bleeding. Additionally alcohol can have additive effects with medicines used to reduce blood pressure. Therefore it is not recommended to drink alcohol while taking Trinomia.

Grapefruit juice contains one or more components that alter how the body uses some medicinal products, including Trinomia. Consuming grapefruit juice should be avoided.

Trinomia should be taken preferably in the evening after dinner (see “How to take Trinomia”).

Pregnancy and breastfeeding

You should not take Trinomia if you are pregnant, think you may be pregnant or are planning to have a baby. If you get pregnant while taking Trinomia, stop taking it immediately and contact your doctor. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

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

Women of child-bearing potential should use effective contraception during treatment.

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

Driving and using machines

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

Trinomia contains lactose and soya lecithin

Trinomia contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Trinomia contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

HOW TO TAKE TRINOMIA

Follow all directions given to you by your doctor and pharmacist carefully.

If you do not understand the instructions on the end of this leaflet, ask your doctor or pharmacist for help.

How to take Trinomia

Take this medicine by mouth preferably in the evening after dinner.

Swallow the capsules whole with liquid.

Do not open, crush or chew the capsules.

How much to take

The usual dose is one capsule once daily.

Your doctor will determine the appropriate strength for you, depending on your condition, your current treatment and your personal risk status.

If you forget to take Trinomia

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 capsule.

If you stop taking Trinomia

Please do not interrupt or stop the treatment with Trinomia until you have spoken with your doctor.

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

WHILE YOU ARE USING TRINOMIA

Things you must do

Use this medicine exactly as your doctor has prescribed.

It is important to keep taking Trinomia as prescribed unless your doctor tells you to stop your treatment.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Trinomia.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

Things you must not do

Do not exceed the recommended daily dose.

Do not take a double dose to make up for the forgotten tablet.

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

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Trinomia.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

The evaluation of side effects is based on the following frequencies:

<i>Very common</i>	affects more than 1 in 10 people
<i>Common</i>	affects less than 1 in 10 people
<i>Uncommon</i>	affects less than 1 in 100 people
<i>Rare</i>	affects less than 1 in 1,000 people
<i>Very rare</i>	affects less than 1 in 10,000 people
<i>Not known</i>	frequency cannot be estimated from the available data

If you experience any of the following you should stop taking Trinomia and seek immediate medical attention

- In very rare occasions tarry stools or vomiting of blood (signs of severe bleeding in the stomach) have been reported.
- In rare occasions hypersensitive reactions of the skin, the respiratory tract, the gastrointestinal tract and the cardiovascular system, especially in case of asthma patients have been reported. The following disease symptoms may occur: low blood pressure, attacks of respiratory distress, rhinitis, nasal

congestion, allergic shock, swelling of the face, tongue and larynx (Quincke's oedema).

- Severe bleeding, such as cerebral bleeding, is rarely or very rarely reported and especially in patients who have uncontrolled high blood pressure and/or simultaneous treatment with anticoagulants (medicines that inhibit the clotting of blood) it can be life-threatening.
- Muscle pain, tenderness, weakness, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.
- In rare occasions hypersensitivity (allergic) reactions have been reported including: Swelling of the face, tongue and throat which make it difficult to swallow or breathe, as well as itching and rashes.
- Serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever. Skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister.
- Rarely, inflammation of the liver with yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stool, liver failure (very rare).
- Rarely, inflammation of the pancreas often with severe abdominal pain.

Tell your doctor if you experience any of the following and they worry you:

- 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.

Side effects with acetylsalicylic acid, atorvastatin or ramipril alone:

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

Acetylsalicylic acid

Very common (may affect more than 1 in 10 people):

- Gastrointestinal complaints such as heartburn, nausea, vomiting, stomach

ache and diarrhoea.

- Insignificant blood loss from the gastrointestinal tract (micro-bleeding).

Atorvastatin

Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

Common (may affect up to 1 in 10 people):

- Inflammation of the nasal passages, pain in the throat, nose bleed.
- Allergic reactions.
- Increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase.
- Headache.
- Nausea, constipation, wind, indigestion, diarrhoea.
- Joint pain, muscle pain and back pain.
- Blood test results that show your liver function can become abnormal.

Ramipril

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 Trinomia 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.

Side effects with acetylsalicylic acid, atorvastatin or ramipril alone:

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

Very common (may affect more than 1 in 10 people):

- Gastrointestinal complaints such as heartburn, nausea, vomiting, stomach ache and diarrhoea.
- Insignificant blood loss from the gastrointestinal tract (micro-bleeding).

Common (may affect up to 1 in 10 people):

- Inflammation of the nasal passages, pain in the throat, nose bleed.
- Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath.
- Chest pain.
- Constipation, wind, indigestion.
- Stomach or gut pain, being sick.
- Headache or feeling tired.
- Feeling dizzy. This is more likely to happen when you start taking Trinomia or start taking a higher dose.
- Fainting, hypotension (abnormally low blood pressure), especially when you stand or sit up quickly.
- Allergic reactions.
- Skin rash with or without raised area.
- Cramps or pain in your muscles.
- Joint pain and back pain.
- Blood test results that show your liver function can become abnormal.
- Increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase.
- Blood tests showing more potassium than usual in your blood.

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.

IF YOU TAKE TOO MUCH TRINOMIA (overdose)

Dizziness and buzzing in the ears, especially in older patients, may be symptoms of a serious intoxication.

Immediately telephone your doctor or Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much TRINOMIA. Do this even if there are no signs of discomfort or poisoning. Take the medicine pack with you. This is so the doctor knows what you have taken.

AFTER USING TRINOMIA

Storage

Keep this medicine out of the sight and reach of children.

Store below 25 Degrees Celsius.

Do not use Trinomia after the expiry date which is stated on the carton and blister.

The expiry date refers to the last day of that month.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PRODUCT DESCRIPTION

What Trinomia looks like

Trinomia 100 mg/20 mg/10 mg hard capsules are size hard shell gelatine capsules (approx. length: 21.7 mm) with opaque pale pink-coloured body and cap, imprinted with “AAR 100/20/10” containing two 50 mg acetylsalicylic white or nearly white film-coated tablet engraved “AS”, two 10 mg atorvastatin greenish-brownish film-coated tablets engraved “AT” and one 10 mg ramipril pale yellow film-coated tablet engraved “R1”.

Trinomia 100 mg/20 mg/5 mg hard capsules are size 0 hard shell gelatine capsules (approx. length: 21.7 mm) with opaque pale pink-coloured cap and opaque light grey-coloured body, imprinted with “AAR 100/20/5” containing two 50 mg acetylsalicylic white or nearly white film-coated tablet engraved “AS”, two 10 mg atorvastatin greenish-brownish film-coated tablets engraved “AT” and one 5 mg ramipril pale yellow film-coated tablet engraved “R5”.

Trinomia 100 mg/20 mg/2.5 mg hard capsules are size 0 hard shell gelatine capsules (approx. length: 21.7 mm) with opaque light grey-coloured body and cap, imprinted with “AAR 100/20/2.5” containing two 50 mg acetylsalicylic white or nearly white film-coated tablet engraved “AS”, two 10 mg atorvastatin greenish-brownish film-coated tablets engraved “AT” and one 2.5 mg ramipril pale yellow film-coated tablet engraved “R2”.

Trinomia 100 mg/20 mg/10 mg hard capsules, Trinomia 100 mg/20 mg/5 mg hard capsules, and Trinomia 100 mg/20 mg/2.5 mg hard capsules are available in blister packs of 28 capsules.

Ingredients

Active Ingredient

The active substances are acetylsalicylic acid, atorvastatin and ramipril.
Each capsule contains:

- 100 mg acetylsalicylic acid, 20 mg atorvastatin (as atorvastatin

calcium trihydrate) and 10 mg ramipril. Or,

- 100 mg acetylsalicylic acid, 20 mg atorvastatin (as atorvastatin calcium trihydrate) and 5 mg ramipril. Or,
- 100 mg acetylsalicylic acid, 20 mg atorvastatin (as atorvastatin calcium trihydrate) and 2.5 mg ramipril.

Excipients (Inactive Ingredients)

Tablet core: microcrystalline cellulose (E460); talc (E553); sodium starch glycolate (type A); lactose monohydrate; pregelatinised starch; calcium carbonate (E170); Hydroxypropylcellulose (E463); Polysorbate 80 (E433); crospovidone (type A); silica colloidal anhydrous; magnesium stearate; hypromellose (E464); sodium stearyl fumarate.

Film-coating: polyvinyl alcohol; titanium dioxide (E171); talc (E553); soya lecithin (E322); xanthan gum (E415); hypromellose (E464); triethyl citrate (E1505); povidone; yellow iron oxide (E172); black iron oxide (E172).

Trinomia 100 mg/20 mg/10 mg Capsule shell: gelatin (E441); titanium dioxide (E171); red iron oxide (E172), shellac glaze, ethanol (traces), iron oxide black, propylene glycol (traces), ammonium hydroxide (traces).

Trinomia 100 mg/20 mg/5 mg Capsule shell: gelatin (E441); titanium dioxide (E171); red iron oxide (E172); black iron oxide (E172), shellac glaze, ethanol (traces), iron oxide black, propylene glycol (traces), ammonium hydroxide (traces).

Trinomia 100 mg/20 mg/2.5 mg Capsule shell: gelatin (E441); titanium dioxide (E171); black iron oxide (E172) shellac glaze, ethanol (traces), iron oxide black, propylene glycol (traces), ammonium hydroxide (traces).

SPONSOR DETAILS

Trinomia is supplied in New Zealand by:

Te Arai BioFarma Ltd

P.O Box 46205

Herne Bay, Auckland 1147

New Zealand

0800 TEARAI (832 724)

This leaflet was prepared in January 2021