5. How to store Triapin

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

Store the tablets in the pack below 25°C.

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 Triapin contains

- The active ingredient in Triapin tablets are: ramipril and felodipine. - Triapin 2.5mg/2.5mg tablets contain 2.5 mg of ramipril and 2.5 mg of felodipine - Triapin 5mg/5mg tablets contain 5 mg of ramipril and 5 mg of felodipine - The other ingredients are: hydroxypropylcellulose, hydroxypropylmethylcellulose, lactose anhydrous, sodium aluminium silicate, sodium stearyl fumarate, iron oxides E172, titanium dioxide E171 and paraffin.

What Triapin looks like and contents of the pack

Triapin 2.5mg/2.5mg tablets are apricot coloured and have “N00” marked on one side and “2.5” marked on the other side.

Triapin 5mg/5mg tablets are reddish-brown and have “N00” marked on one side and “5” on the other side.

Both strengths of Triapin come in blister packs containing 10, 14, 15, 21, 28, 30, 50, 98 and 100 tablets or in bottles containing 60 tablets.

Not all pack sizes may be marketed.

Market Authorisation Holder:

Sanofi
One Onslow Street
Guildford
GU1 4YS
email: uk-medicalinformation@sanofi.com

Manufacturers:

Ch Shin Private Co Ltd
Veveseghaz
Hungary

This leaflet was last revised in February 2018

6. Package leaflet: information for the user

Triapin 2.5 mg / 2.5 mg and Triapin 5 mg / 5 mg prolonged release tablets

ramipril/felodipine

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 Triapin is and what it is used for

2. What you need to know before you take Triapin

3. How to take Triapin

4. Possible side effects

5. How to store Triapin

6. Contents of the pack and other information

What Triapin is and what is it used for

Triapin 2.5 mg / 2.5 mg and Triapin 5 mg / 5 mg prolonged release tablets (also called Triapin tablets in this leaflet) both contain two medicines called ramipril and felodipine.

Ramipril belongs to a group of medicines called ‘angiotensin converting enzyme inhibitors’ (ACE inhibitors). It works by stopping the production of substances that raise blood pressure and makes your blood vessels relax and widen. Felodipine belongs to a group of medicines called ‘calcium channel antagonists’. It makes your blood vessels relax and widen. This helps to lower your blood pressure.

Triapin tablets are used to treat high blood pressure (hypertension). High blood pressure can mean you are at risk of developing heart and blood vessel problems (such as heart attack or stroke) or kidney problems.

Triapin tablets help to control your blood pressure and lower the risk of these problems.

What do you need to know before you take Triapin

Do not take Triapin tablets if:

- You are allergic to:
  - ramipril or any other ACE inhibitor
  - felodipine or any other calcium antagonist
  - any of the other ingredients of this medicine (listed in section 6)

- 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.

- You have a severe kidney problem

- You are having dialysis

- You have a severe liver problem

- You are pregnant, trying to get pregnant or breast-feeding (see ‘Pregnancy and breast-feeding’ below)

- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Triapin tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Triapin tablets if:

- You have kidney problems, diabetes mellitus or are taking medicines which increase potassium.

- You may carry out regular blood tests, particularly for checking the levels of potassium in your blood.

- 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.

- 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, naproxin (NEP) inhibitors (such as ralatadinit) or sacubitril/valsartan. For sacubitril/valsartan, see section 2 ‘Do not take Triapin tablets if’.

- You have kidney problems.

- You have narrowing of the main blood vessel leading from the heart (aortic stenosis) or heart muscle disease (hypertrophic cardiomyopathy).

- You have any other heart problem.

- You have systemic lupus erythematosus or scleroderma.

- You suffer from liver problems.

- You are going to have an anesthetic or surgery.

- You are taking medicines which lower the number of certain blood cells.

- You are black because the medicine may have less effect.

- You have ever had a heart attack (acute myocardial infarction) or a stroke (disturbance of the blood circulation in the brain).

- You have a heart condition known as atrioventricular block II or III, a heart attack (acute myocardial infarction) or a stroke (disturbance of the blood circulation in the brain).

- You have heart failure (chronic heart failure in adults).

- You have heart problems such as heart failure, obstructions in your heart, angina which is unstable, a heart condition known as atrioventricular block II or III, a heart attack (acute myocardial infarction) or a stroke (disturbance of the blood circulation in the brain).

- You have a heart condition known as atrioventricular block II or III.

- You have heart failure (chronic heart failure in adults).

- You have heart problems such as heart failure, obstructions in your heart, angina which is unstable, a heart condition known as atrioventricular block II or III, a heart attack (acute myocardial infarction) or a stroke (disturbance of the blood circulation in the brain).

- You have ever had a heart attack (acute myocardial infarction) or a stroke (disturbance of the blood circulation in the brain).

- You have heart problems such as heart failure, obstructions in your heart, angina which is unstable, a heart condition known as atrioventricular block II or III, a heart attack (acute myocardial infarction) or a stroke (disturbance of the blood circulation in the brain).

- You have a heart condition known as atrioventricular block II or III.

- You have heart failure (chronic heart failure in adults).

- You have heart problems such as heart failure, obstructions in your heart, angina which is unstable, a heart condition known as atrioventricular block II or III, a heart attack (acute myocardial infarction) or a stroke (disturbance of the blood circulation in the brain).

- You have a heart condition known as atrioventricular block II or III.

- You have heart failure (chronic heart failure in adults).

- You have heart problems such as heart failure, obstructions in your heart, angina which is unstable, a heart condition known as atrioventricular block II or III, a heart attack (acute myocardial infarction) or a stroke (disturbance of the blood circulation in the brain).

- You have a heart condition known as atrioventricular block II or III.

- You have heart failure (chronic heart failure in adults).

- You have heart problems such as heart failure, obstructions in your heart, angina which is unstable, a heart condition known as atrioventricular block II or III, a heart attack (acute myocardial infarction) or a stroke (disturbance of the blood circulation in the brain).

- You have a heart condition known as atrioventricular block II or III.
• You have swelling in your gums which may be a sign of gingivitis or periodontitis. Careful dental hygiene may be necessary to avoid additional gum problems, such as a condition which increases the size of your gums.
• You are taking any of the following medicines used to treat high blood pressure:
  - angiotensin II receptor blocker (ARBs) (also known as sartans) for example valsartan, telmisartan, irbesartan, in particular if you have diabetes-related kidney problems.

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 Triapin tablets".

Other medicines and Triapin tablets
Tell your doctor or pharmacist if you are using, or have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Triapin tablets can affect the way some other medicines work. Also some medicines can affect the way Triapin tablets work.

In particular, tell your doctor if you are taking or being treated with any of the following:

- Sulfirbital/valhurib - used for treating a type of long-term (chronic) heart failure in adults (see section 2. Do not take Triapin tablets if)
- Medicines for lowering high blood pressure (antihypertensives), including those containing aliskiren, telmisartan, irbesartan, in particular if you have diabetes-related kidney problems.
- Medicines to treat HIV infection
- Procainamide – used for treating heart rhythm disorders
- Water tablets (diuretics) which can cause high blood potassium such as amiloride, spironolactone, triamterene
- Lignepin – used for thinning the blood
- Lithium preparations - used to treat mania, depression and manic-depressive illness
- Theophylline or theophylline derivatives and barbiturates. These medicines are usually used to treat epilepsy, fits and convulsions. Barbiturates are also used for sleeping
- Thrombolytics such as adrenaline, noradrenaline or ephedrine (medicines which act on the heart and blood vessels)
- Erythromycin, itraconazole, ketoconazole used for treating infections
- Allopurinol – used for treatment of hyperuricemia
- Non-steroidal anti-inflammatory drugs (NSAIDs) – used to treat cancer
- Insulin, glibenclamide, metformin, vildagliptin, and other medicines used for diabetes mellitus
- Glucorticoids (steroids)
- Potassium salts
- Methotrexate alone or in combination with sulfamethoxazole used for infections
- St John’s Wort

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 Triapin tablets" and "Warnings and precautions")
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Triapin tablets.

Triapin tablets with food and drink
Taking this medicine with alcohol may increase the effect of your medicine
- Taking this medicine with grapefruit juice is not recommended
- Increasing the amount of salt in your diet may lower the effect of this medicine
- Take the tablets on an empty stomach or after eating a light meal

Pregnancy and breastfeeding

Do not take Triapin tablets if:

- You are pregnant, might become pregnant or think you are pregnant. You should not take Triapin tablets. Consult your doctor before you become pregnant
- Your doctor may start you on Triapin 2.5mg/2.5mg tablet taken once a day
- The maximum dose is either 2 Triapin 2.5mg/2.5mg tablets once a day or 1 Triapin 5mg/5mg tablet once a day

- You are already taking diuretics (water tablets), your doctor may stop or reduce the amount of the diuretic you take before beginning treatment with Triapin tablets.

Use in children
Do not give Triapin to children.
- If you take more Triapin than you should, tell a doctor or go to the nearest hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. You may feel dizzy and light-headed because your blood pressure is too low.

If you forget to take Triapin:

- If you forget to take a dose and remember on the same day
- If you forget to take a dose and remember this the next day
- Take only your usual dose of Triapin
- Do not take a double dose to make up for a forgotten dose

If you stop taking Triapin:

- Keep taking treatment until your doctor tells you to stop.
- If you stop taking Triapin tablets with food and drink
- If you forget to take a dose and remember on the same day
- If you forget to take a dose and remember this the next day
- Take only your usual dose of Triapin
- 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 Triapin tablets 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
- 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, unexplained or severe headache (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, bleeding on the skin or gums, nosebleeds more easily than usual, sore throat and fever, feeling tired, faint, dizzy or having pale skin. These can be signs of blood or bone marrow problems
- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis (inflammation of the pancreas)
- Fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, yellowing of your skin or eyes (jaundice). These can be signs of liver problems such as hepatitis (inflammation of the liver) or liver damage.

Other side effects include:

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

Very Common (may affect more than 1 in 10 people)
- Swollen arms and legs. This may be a sign of your body holding on to more water than usual

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 Triapin tablets or start taking a higher dose
- Fainting, hypotension (abnormally low blood pressure), feeling dizzy or light-headed because your blood pressure is too low.
- Feeling tired, flushing
- Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath
- Stomach or gut pain, diarrhoea, indigestion, feeling or looking sick
- Skin rash with or without raised area
- 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)
- 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
- Pass more water (urine) than usual over the day
- Sweating more than usual
- Loss or decrease of appetite (anorexia)
Other medicines and Triapin tablets

Tell your doctor or pharmacist if you are using, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Triapin tablets can affect the way some other medicines work. Also some medicines can affect the way Triapin tablets work.

In particular, tell your doctor if you are taking or being treated with any of the following:

- Sacubitril/valsartan - used for treating a type of long-term (chronic) heart failure
- Rifampicin - used for treatment of tuberculosis
- Temsirolimus (for cancer)
- Glucocorticoids ('steroids')
- Cytostatics – used to treat cancer
- Theophylline - used for treating asthma
- Lithium preparations - used to treat mania, depression
- Lithium preparations - used to treat mania, depression
- Heparin – used for thinning the blood
- Water tablets (diuretics) which can cause high pressure, and the amount of electrolytes (e.g. potassium)
- Medicines to treat HIV infection
- Other medicines used for diabetes mellitus (antihypertensives), including those containing aliskiren, irbesartan), in particular if you have diabetes-related kidney problems.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium)

Triapin tablets contain lactose, a type of sugar. If you are using a medicine containing lactose, tell your doctor or pharmacist if you have intolerance to dairy products (lactose intolerance).

Tell your doctor or pharmacist if you are using, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Triapin tablets can affect the way some other medicines work. Also some medicines can affect the way Triapin tablets work.

In particular, tell your doctor if you are taking or being treated with any of the following:

- Sacubitril/valsartan - used for treating a type of long-term (chronic) heart failure
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- Other medicines used for diabetes mellitus (antihypertensives), including those containing aliskiren, irbesartan), in particular if you have diabetes-related kidney problems.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium)
5. How to store Triapin
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 after EXP. The expiry date refers to the last day of that month.

Store the tablets in the pack below 25°C.

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 Triapin contains
The active ingredients in Triapin tablets are: ramipril and felodipine.
- Triapin 2.5mg/2.5mg tablets contain 2.5 mg of ramipril and 2.5 mg of felodipine
- Triapin 5mg/5mg tablets contain 5 mg of ramipril and 5 mg of felodipine
- The other ingredients are: hydroxypropylcellulose, hydroxypropylmethylcellulose, lactose anhydrous, mMagnesium stearate, iron oxides E172, titanium dioxide E171 and paraffin.

What Triapin looks like and contents of the pack
Triapin 2.5mg/2.5mg tablets are apricot coloured and have “N001” marked on one side and “2.5” marked on the other side.

Triapin 5mg/5mg tablets are reddish-brown and have “N002” marked on one side and “5” on the other side.

Both strengths of Triapin come in blister packs containing 10, 14, 15, 21, 28, 30, 50, 98 and 100 tablets or in bottles containing 56, 250 and 280 tablets. Not all pack sizes may be marketed.

Market Authorisation Holder:
Sanofi
One Oriel Street
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GU1 4YV
Tel: 0845 372 7101
email: uk-medicalinformation@sanom.com

Manufacturers:
Chinoin Private Co. Ltd
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