

TICALET 60MG, 90MG FILM-COATED TABLETS

(Ticagrelor 60mg, 90mg)

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What **Ticalet** is used for

Ticalet contains an active substance called ticagrelor. This belongs to a group of medicines called antiplatelet medicines.

Ticalet 60 mg, in combination with acetylsalicylic acid (another antiplatelet agent) is to be used in adults only. You have been given this medicine because you have:

- had a heart attack, over a year ago.
- coronary artery disease and type 2 diabetes, with no previous heart attacks, and have previously had a procedure to open a blocked or narrowed heart blood vessel (percutaneous coronary intervention or PCI). This may have included placement of a small tube (stent) to keep the blocked or narrowed blood vessel open.

Ticalet 90 mg, in combination with acetylsalicylic acid (another antiplatelet agent) is to be used in adults only. You have been given this medicine, because you have had:

- a heart attack, or
- unstable angina (angina or chest pain that is not well controlled).
- stroke (acute ischemic stroke) or mini-stroke (transient ischemic attack or TIA)

Ticalet reduces the chances of you having another heart attack, stroke or dying from a disease related to your heart or blood vessels.

How **Ticalet** works

Ticalet affects cells called 'platelets' (also called thrombocytes). These very small blood cells help stop bleeding by clumping together to plug tiny holes in blood vessels that are cut or damaged.

However, platelets can also form clots inside diseased blood vessels in the heart and brain. This can be very dangerous because:

- the clot can cut off the blood supply completely; this can cause a heart attack (myocardial infarction) or stroke, or
- the clot can partly block the blood vessels to the heart; this reduces the blood flow to the heart and can cause chest pain which comes and goes (called 'unstable angina').

Ticalet helps stop the clumping of platelets. This reduces the chance of a blood clot forming that can reduce blood flow.

Before you use **Ticalet**

– When you must not use it

- if you are allergic to ticagrelor or any of the other ingredients of **Ticalet** listed at the end of this section.
- if you are bleeding now.
- if you have had a stroke caused by bleeding in the brain.
- if you have severe liver disease.
- if you are taking any of the following medicines:
 - ketoconazole (used to treat fungal infections)
 - clarithromycin (used to treat bacterial infections)
 - nefazodone (an antidepressant)
 - ritonavir and atazanavir (used to treat HIV infection and AIDS)

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

– Before you start to use it

Talk to your doctor or pharmacist before taking **Ticalet** if:

- You have an increased risk of bleeding because of:

- a recent serious injury
- recent surgery (including dental work, ask your dentist about this)
- you have condition that affects blood clotting
- recent bleeding from your stomach or gut (such as a stomach ulcer or colon 'polyps')
- You are due to have surgery (including dental work) at any time while taking ticagrelor. This is because of the increased risk of bleeding. Your doctor may want you to stop taking this medicine 5 days prior to surgery.
- Your heart rate is abnormally low (usually lower than 60 beats per minute) and you do not already have in place a device that paces your heart (pacemaker).
- You have asthma or other lung problems or breathing difficulties.
- You develop irregular breathing patterns such as speeding up, slowing down or short pauses in breathing. Your doctor will decide if you need further evaluation.
- You have had any problems with your liver or have previously had any disease which may have affected your liver.
- You have had a blood test that showed more than the usual amount of uric acid.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using **Ticalet**.

If you have coronary artery disease and type 2 diabetes, your doctor should regularly monitor if your treatment is appropriate for you. Your doctor will discuss any risks and ways to prevent possible side effects while you are taking **Ticalet**.

If you are taking both **Ticalet** and heparin:

- Your doctor may require a sample of your blood for diagnostic tests if they suspect a rare platelet disorder caused by heparin. It is important that you inform your doctor that you are taking both **Ticalet** and heparin, as **Ticalet** may affect the diagnostic test.

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Children and adolescents

Ticalet is not recommended for children and adolescents under 18 years.

Pregnancy

It is not recommended to use **Ticalet** if you are pregnant or may become pregnant. Women should use appropriate contraceptive measures to avoid pregnancy while taking this medicine.

Talk to your doctor before taking this medicine if you are breast-feeding. Your doctor will discuss with you the benefits and risks of taking **Ticalet** during this time.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

– Taking other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because **Ticalet** can affect the way some medicines work and some medicines can have an effect on **Ticalet**.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- rosuvastatin (a medicine to treat high cholesterol)
- more than 40 mg daily of either simvastatin or lovastatin (medicines used to treat high cholesterol).
- rifampicin (an antibiotic)
- phenytoin, carbamazepine and phenobarbital (used to control seizures)
- digoxin (used to treat heart failure)
- cyclosporine (used to lessen your body's defenses)
- quinidine and diltiazem (used to treat abnormal heart rhythms)
- beta blockers and verapamil (used to treat high blood pressure)
- morphine and other opioids (used to treat severe pain)

Tell your doctor or pharmacist if you are taking any of the following medicines that increase your risk of bleeding.

- 'oral anticoagulants' often referred to as 'blood thinners' which include warfarin.
- Non-Steroidal Anti-Inflammatory Drugs (abbreviated as NSAIDs) often taken as painkillers such as ibuprofen and naproxen.
- Selective Serotonin Reuptake Inhibitors (abbreviated as SSRIs) taken as antidepressants such as paroxetine, sertraline and citalopram.
- other medicines such as ketoconazole (used to treat fungal infections), clarithromycin (used to treat bacterial infections), nefazodone (an antidepressant), ritonavir and atazanavir (used to treat HIV infection and AIDS), cisapride (used to treat heartburn), ergot alkaloids (used to treat migraines and headaches).

Also tell your doctor that because you are taking **Ticalet** you may have an increased risk of bleeding if your doctor gives you fibrinolytics, often called 'clot dissolvers', such as streptokinase or alteplase.

How to use Ticalet

– How much to use

If you are taking Ticalet 60 mg

The usual dose is one tablet of 60 mg twice a day.

Your doctor will usually also tell you to take acetylsalicylic acid. This is a substance present in many medicines used to prevent blood clotting. Your doctor will tell you how much to take (usually between 75-150 mg daily).

If you are taking Ticalet 90 mg

Heart attack or unstable angina

The starting dose is two tablets at the same time (loading dose of 180 mg). This dose will usually be given to you in the hospital.

After this starting dose, the usual dose is one tablet of 90 mg twice a day for up to 12 months unless your doctor tells you differently.

Your doctor will usually also tell you to take acetylsalicylic acid. This is a

substance present in many medicines used to prevent blood clotting. Your doctor will tell you how much to take (usually between 75 - 150 mg daily).

Stroke or mini-stroke

The starting dose is two tablets at the same time (loading dose of 180 mg). This dose will usually be given to you in the hospital.

After this starting dose, the usual dose is one tablet of 90 mg twice a day for up to 30 days.

A starting dose of acetylsalicylic acid (300-325mg) usually will be given together with **Ticalet 90** in the hospital. After this starting dose, take 75-100mg of acetylsalicylic acid daily together with **Ticalet 90**.

– When to use it

Take this medicine around the same time every day (for example, one tablet in the morning and one in the evening).

You can take the tablet with or without food.

If you have trouble swallowing the tablet you can crush it and mix with water as follows:

- Crush the tablet to a fine powder.
- Pour the powder into half a glass of water.
- Stir and drink immediately.
- To make sure there is no medicine left, rinse the empty glass with another half a glass of water and drink it.

If you are in the hospital you may be given this tablet mixed with some water and given through a tube via the nose (nasogastric tube).

– How long to use it

Your doctor will advise you on how long you should continue to take your medicine.

You should continue using **Ticalet** until your doctor tells you to stop.

– If you forget to use it

If you forget to take a dose, just take your next dose as normal.

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Do not take a double dose (two doses at the same time) to make up for the forgotten dose.

– If you use too much (overdose)

If you take more **Ticalet** than you should, talk to a doctor or go to hospital straight away. Take the medicine pack with you. You may be at increased risk of bleeding.

While you are using Ticalet

– Things you must do

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

– Things you must not do

Do not stop taking **Ticalet** or alter the dose, without first checking with your doctor.

Take this medicine on a regular basis and for as long as your doctor keeps prescribing it. If you stop taking **Ticalet**, it may increase your chances of having another heart attack or stroke or dying from a disease related to your heart or blood vessels.

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

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

– Things to be careful of

Driving and using machines

Ticalet is not likely to affect your ability to drive or use machines. If you feel dizzy or confused while taking this medicine, be careful while driving or using machines.

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Ticalet affects blood clotting, so most

side effects are related to bleeding.

Bleeding may occur in any part of the body. Some bleeding is common (like bruising and nose-bleeds). Severe bleeding is uncommon, but can be life threatening.

If any of the following happen, stop taking **Ticalet** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- **Bleeding into the brain or inside the skull is an uncommon side effect, and may cause signs of a stroke such as:**

- sudden numbness or weakness of your arm, leg or face, especially if only on one side of the body
- sudden confusion, difficulty speaking or understanding others
- sudden difficulty in walking or loss of balance or co-ordination
- suddenly feeling dizzy or sudden severe headache with no known cause.

- **Signs of bleeding such as:**

- bleeding that is severe or that you cannot control
- unexpected bleeding or bleeding that lasts a long time
- pink, red, or brown urine
- vomiting red blood or your vomit looks like 'coffee grounds'
- red or black stools (look like tar)
- coughing up or vomiting blood clots.

- **Fainting (syncope)**

- a temporary loss of consciousness due to sudden drop in blood flow to the brain (common).

- **Signs of a blood clotting problem called Thrombotic Thrombocytopenic Purpura (TTP) such as:**

- Fever and purplish spots (called purpura) on the skin or in the mouth, with or without yellowing of the skin or eyes (jaundice), unexplained extreme tiredness or confusion.

Tell your doctor as soon as possible if you notice any of the following:

- Feeling short of breath - this is very common. It might be due to your

heart disease or another cause, or it might be a side effect of **Ticalet**. **Ticalet** related breathlessness is generally mild and characterised as a sudden, unexpected hunger for air usually occurring at rest and may appear in the first weeks of therapy and for many may disappear. If you are feeling of shortness of breath gets worse or lasts a long time, tell your doctor. Your doctor will decide if it needs treatment or further investigations.

Other side effects:

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

- High level of uric acid in your blood (as seen in tests)
- Bleeding caused by blood disorders

Common (may affect up to 1 in 10 people)

- Bruising
- Headache
- Feeling dizzy or like the room is spinning
- Diarrhoea or indigestion
- Feeling sick (nausea)
- Constipation
- Rash
- Itching
- Severe pain and swelling in your joints – these are signs of gout
- Feeling dizzy or light-headed, or having blurred vision – these are signs of low blood pressure
- Nosebleed
- Bleeding after surgery or from cuts (for example while shaving) and wounds more than is normal
- Bleeding from your stomach lining (ulcer)
- Bleeding gums

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→

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Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Ticalet

– Storage

Store below 30°C, protected from moisture.

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

– Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Product description

– What it looks like

Ticalet 60mg

Round, biconvex, pink, film-coated tablets debossed with “60” above “T” on one side.

Ticalet 90mg

Round, biconvex, yellow film-coated Tablets debossed with “90” above “T” on one side.

Ticalet is available as 10 Tablets are packed in ALU/PVC/PVDC blister pack and such 3 blisters are further packed in carton along with packing insert.

– Ingredients

– **Active ingredient:**

Each Film coated tablet contains:

Ticagrelor.....60/90 mg

– **Inactive ingredients:**

Lactose (Pharmatose 200 M), Microcrystalline cellulose (PH 102), Hydroxypropyl cellulose (Klucel EXF), Croscarmellose Sodium (Ac-di-sol), Purified water, Magnesium stearate, Opadry complete film coating system 03B32376 Yellow or Opadry complete film coating system 03B34604 pink.

Sodium Content

Ticalet contain less than 1 mmol of sodium (23 mg) per tablet that is to say it is essentially ‘sodium-free’.

Registration Number:

Ticalet 60mg MALXXXXXXXXXAZ

Ticalet 90mg MALXXXXXXXXXAZ

Manufacturer

Sun Pharmaceuticals Industries Ltd.
Village Ganguwala, Paonta Sahib-173025
District Sirmour, Himachal Pradesh
India

Product Registration Holder

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