

TGSON-60

Ticagrelor Film Coated Tablets 60 mg

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What is TGSON-60 used for

TGSON-60 contains an active substance called ticagrelor. This belongs to a group of medicines called antiplatelet medicines.

TGSON-60 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.

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

How TGSON-60 works

TGSON-60 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').

TGSON-60 helps stop the clumping of platelets. This reduces the chance of a blood clot forming that can reduce blood flow.

Before you use TGSON-60

-When you must not use it

- You are allergic to ticagrelor or any of the other ingredients of this medicine (listed in section "Ingredients").
- You are bleeding now.
- You have had a stroke caused by bleeding in the brain.
- You have severe liver disease.
- 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 TGSON-60 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 TGSON-60 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 a 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 TGSON-60. 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 taking this medicine.

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 TGSON-60.

If you are taking both TGSON-60 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 TGSON-60 and heparin, as TGSON-60 may affect the diagnostic test.

Use in children

TGSON-60 is not recommended for children and adolescents under 18 years.

-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 TGSON-60 can affect the way some medicines work and some medicines can have an effect on TGSON-60.

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)

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- 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)

In particular, 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 TGSON-60, 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 TGSON-60

-How much to use

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).

-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

Continue taking TGSON-60 as long as your doctor tells you.

-If you forget to use it

- You can check when you last took a tablet of TGSON-60 by looking on the blister. This will tell you whether you have taken the dose.
- If you forget to take a dose, just take your next dose as normal.
- 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 TGSON-60 than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. You may be at increased risk of bleeding.

While you are using it

-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 TGSON-60 without talking to your doctor. Take this medicine on a regular basis and for as long as your doctor keeps prescribing it.

If you stop taking TGSON-60, 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.

-Things to be careful of

Pregnancy

It is not recommended to use TGSON-60 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 TGSON-60 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.

Driving and using machines

TGSON-60 is not likely to affect your ability to drive or use machines. If you feel dizzy or confusion 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:

TGSON-60 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.

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See a doctor straight away if you notice any of the following – you may need urgent medical treatment:

- **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

Discuss with your doctor 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 TGSON-60. TGSON-60-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 your 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 possible 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

Uncommon (may affect up to 1 in 100 people)

- Allergic reaction – a rash, itching, or a swollen face or swollen lips/tongue may be signs of an allergic reaction
- Confusion
- Visual problems caused by blood in your eye
- Vaginal bleeding that is heavier, or happens at different times, than your normal period (menstrual) bleeding
- Bleeding into your joints and muscles causing painful swelling
- Blood in your ear
- Internal bleeding, this may cause dizziness or light-headedness

Not known (cannot be estimated from the available data)

- Abnormally low heart rate (usually lower than 60 beats per minute)

If you get any side effects or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist, but do not stop taking TGSON-60 until you have spoken to them.

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

Storage and Disposal of TGSON-60

-Storage

- Store at a temperature not exceeding 30°C.
- Keep medicine out of reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. 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 throw away medicines you no longer use. These measures will help to protect the environment.

Product Description

-What it looks like

Film coated tablet (tablet): Light pink to pink, round, biconvex film coated tablets debossed with “C12” on one side and plain on other side.

TGSON-60 is available in Alu PVC/PVDC blisters in cartons of 1 x 14 tablets and 6 x 10 tablets.

-Ingredients

Active ingredient(s)

The active substance is ticagrelor. Each film coated tablet contains 60 mg of ticagrelor.

Inactive ingredient(s)

The other ingredients are:

- Tablet core: Mannitol, Calcium hydrogen phosphate dihydrate, Hydroxy Propyl Cellulose, Croscarmellose Sodium, Magnesium Stearate
- Tablet film coating: Opadry Pink (03B540257) [Composition of Opadry Pink (03B540257): HPMC 2910/ Hypromellose, Titanium

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Dioxide, Macrogol/ PEG, Iron
Oxide Red, Black Iron Oxide]

-MAL number

MALXXXXXXXXX

Manufacturer

Unison Pharmaceuticals Private Limited
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Product Registration Holder

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