

TICAGRELOR SANDOZ[®]

ticagrelor tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Ticagrelor Sandoz. It does not contain all the available information that is known about Ticagrelor Sandoz.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ticagrelor Sandoz against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Ticagrelor Sandoz is used for

Ticagrelor Sandoz in combination with aspirin is to be used in adults only. You have been given Ticagrelor Sandoz because you have had:

- a heart attack, or
- unstable angina (angina or chest pain that is not well controlled)

Ticagrelor Sandoz reduces the chances of having another heart attack or of dying from a disease related to your heart or blood vessels.

How Ticagrelor Sandoz works

Ticagrelor Sandoz contains a medicine called ticagrelor. This belongs to a group of medicines called anti-platelet medicines.

Platelets (also called thrombocytes) are very small cells in your blood that help to stop bleeding. When a blood vessel is damaged, they clump together to help form a blood clot. This stops bleeding.

However, clots can also form inside a damaged blood vessel. 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
- the clot can partly block the blood vessels to the heart – this reduces the blood flow to the heart. This can cause chest pain which comes and goes (called ‘unstable angina’)

Ticagrelor Sandoz helps stop the clumping of platelets. This reduces the chance of a blood clot forming that can block a blood vessel. This means that Ticagrelor Sandoz reduces the chance of you having another heart attack, chest pain or stroke.

Your doctor will usually also tell you to take acetylsalicylic acid (aspirin). This is another medicine, which affects platelets.

Your doctor will have explained why you are being treated with Ticagrelor

Sandoz and told you what dose to take.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Ticagrelor Sandoz is only available on a doctor’s prescription.

There is no evidence that Ticagrelor Sandoz is addictive.

Before you take Ticagrelor Sandoz

When you must not take it

You should not take Ticagrelor Sandoz if:

- **you have an allergy to any medicine containing ticagrelor or any of the ingredients listed at the end of the leaflet.**

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

- **you have problems with bleeding, such as bleeding in**

your stomach or gut from an ulcer.

- you have moderate to severe liver disease.
- you have had a stroke caused by bleeding in the brain or a history of bleeding in the brain.
- 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).
- the use by (expiry) date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If you take this product after expiry date has passed, it may not work.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not take Ticagrelor Sandoz to treat any other complaint unless your doctor advises you to. Do not give this medicine to anyone else.

Ticagrelor Sandoz is not recommended for children under 18 years of age, as its safety and effectiveness in children have not been established.

Do not take Ticagrelor Sandoz if any of the above apply to you. If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor, dentist or pharmacist if:

- you have allergies to any other medicines, foods, preservatives or dyes
- you have an increased risk of bleeding because of:
 - a recent serious injury

- recent surgery (including dental work)
- recent bleeding from your stomach or gut (such as stomach ulcer or colon polyps)
- you have a condition that affects blood clotting

- you have asthma or other lung problem or breathing difficulties
- you are due to have surgery (including dental work) at any time while taking Ticagrelor Sandoz.

This is because of the increased risk of bleeding. Your doctor may want you to stop taking Ticagrelor Sandoz 5 days prior to surgery.

- you have or have had high uric acid
- your heart rate is abnormally low (usually lower than 60 beats per minute) and you do not already have a place a device that paces your heart (pacemaker)
- you have or have had any medical conditions
- you are pregnant or intend to become pregnant
- It is not recommended you take Ticagrelor Sandoz. Your doctor will discuss the risks and benefits of taking Ticagrelor Sandoz during pregnancy.
- you are breast feeding or intend to breast feed.

It is not recommended you take Ticagrelor Sandoz. Your doctor will discuss the risks and benefits of taking Ticagrelor Sandoz during breast feeding.

If you have not told your doctor, dentist or pharmacist about any of the above, tell them before you start taking Ticagrelor Sandoz.

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.

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

- more than 40 mg daily of simvastatin or lovastatin (medicines used to treat high cholesterol)
- rifampin (an antibiotic)
- phenytoin, carbamazepine and phenobarbital (used to control seizures)
- dexamethasone (used to treat inflammatory and autoimmune conditions)
- digoxin (used to treat heart failure)
- ciclosporin (used to lessen your body's defences)
- quinidine and diltiazem (used to treat abnormal heart rhythms)
- adenosine (used to treat irregular heart rate)
- ergotamine (used to treat migraine)
- beta blockers and verapamil (used to treat high blood pressure)
- morphine (used to relieve pain)

Tell your doctor or pharmacist if you are taking any medicines that may increase your risk of bleeding. These medicines include:

- “oral anticoagulants”, often referred to as “blood thinners”, which include aspirin, warfarin, clopidogrel and prasugrel.
- “fibrinolytics” and “thrombolytics”, often referred to as “clot-dissolvers”, which include streptokinase and tenecteplase
- non-steroidal anti-inflammatory drugs (NSAIDs) often taken as pain killers such as ibuprofen and naproxen.

- selective serotonin reuptake inhibitors (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).

You may need different amounts of your medicines, or may need to take different medicines.

If you are unsure about any medicine you are taking you should check with your doctor or pharmacist. They will have more information on medicines to be careful with or avoid while taking Ticagrelor Sandoz.

How to take Ticagrelor Sandoz

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

They may differ from the information contained in this leaflet.

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

How much to take

The dose of Ticagrelor Sandoz you take will depend on your condition. Your doctor will tell you the correct dose to use.

If you had a recent heart attack or unstable angina (angina or chest pain that is not well controlled). 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 12 months unless your doctor tells you differently. After one year your doctor may continue your treatment with a lower dose of 60 mg tablet twice a day.

If you had a heart attack over a year ago, the usual dose is one 60 mg tablet twice a day. Continue taking Ticagrelor Sandoz as long as your doctor tells you.

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

Your doctor will usually also tell you to take low dose aspirin. 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).

How to take it

Swallow each tablet whole with a drink of water.

If you have trouble swallowing Ticagrelor Sandoz film-coated tablets you can crush them and mix with water as follows:

- Crush the tablet(s) to a fine powder using a mortar and pestle or other crushing device.
- Add half a glass of water (approximately 100 mL) to the mortar and pestle/crushing device and stir before pouring the liquid into a glass and drinking immediately.
- For the remaining medicine, add another 100 mL to mortar and pestle/crushing device and stir. Pour the liquid into a glass and drink immediately. Make sure you also stir the liquid in the glass before you drink it.

If you are using a nasogastric tube because you cannot swallow at all:

- Crush tablets in mortar and pestle/crushing device to a fine powder.
- Add 50 mL of water to the mortar and pestle/crushing device and stir before withdrawing the

mixture into a syringe and administering the liquid through a nasogastric tube.

- For the remaining medicine, add another 50 mL to mortar and pestle/crushing device and stir before withdrawing the mixture into the syringe and administering through a nasogastric tube.
- Once all the medicine is used, flush the nasogastric tube with approximately 25 mL of water to deliver any remaining contents of the medicine in the tube into the stomach.
- you can check when you last took a tablet of Ticagrelor Sandoz by looking on the blister. There is a sun (for the morning) and a moon (for the evening). This will tell you whether you have taken the dose.

How long to take it

You should take Ticagrelor Sandoz for as long as your doctor tells you to.

If you forget to take it

If you forget to take a dose, take your next dose as normal. Then go back to taking it as you would normally.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON (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 Ticagrelor Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many Ticagrelor Sandoz tablets you may be at an increased risk of bleeding.

While you are taking Ticagrelor Sandoz

Things you must do

- **Take Ticagrelor Sandoz exactly as your doctor has told you to.**
- **Tell all doctors, dentists and pharmacists who are treating you that you are taking Ticagrelor Sandoz.**
- **If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking Ticagrelor Sandoz.**
- **Tell your doctor if you become pregnant while you are taking Ticagrelor Sandoz.**
- **Tell your doctor if you decide to breast feed your baby.**

Things you must not do

- **Do not stop taking Ticagrelor Sandoz without talking to your doctor. Take it for as long as your doctor keeps prescribing it. If you want to stop taking Ticagrelor Sandoz, talk to your doctor first.**

This is because the benefits of Ticagrelor Sandoz are based on you taking it all the time. If you stop taking Ticagrelor Sandoz without talking to your doctor it may increase the chance of a heart attack or stroke or a blood clot forming.

- **Do not give this medicine to anyone else, even if they have symptoms that seem similar to yours.**

Things to be careful of

Be careful driving or operating machinery.

Ticagrelor Sandoz is not likely to affect your ability to drive or use machines. You are being treated because you had a heart attack or unstable angina and you may experience dizziness and confusion. If you have these symptoms, you should be cautious while driving or using machines.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ticagrelor Sandoz.

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 the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- **Feeling short of breath**

This is very common (affects more than 1 in 10 people). It might be due to your heart disease or other cause, or it might be a side effect of Ticagrelor Sandoz. 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.
- **Signs of irregular breathing (Central sleep apnoea and Cheyne-Stokes respiration)**

This has been reported in a small number of patients taking ticagrelor (frequency cannot be estimated from the available

data). Central sleep apnoea is associated with irregular breathing and may occur in patients with heart disease, stroke or other causes. Tell your doctor if 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.

- Bruising
- Nosebleed
- Headache
- Stomach pain
- Constipation, diarrhoea or indigestion
- Feeling or being sick (nausea)
- Rash
- Inflamed stomach (gastritis)
- A tingling feeling
- Fainting

Tell your doctor immediately if you notice any of the following as you may need urgent medical treatment:

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.

These are signs of a kind of stroke caused by bleeding into the brain. This is uncommon (affects less than 1 in 100 people).

Signs of bleeding, including:

- bleeding that is severe or that you cannot control
- unexpected bleeding or bleeding that lasts a long time
- pink, red or brown urine

- black stools (looks like tar) or red blood in your stools
- visual disturbance caused by blood in your eye
- coughing up or vomiting red blood or your vomit looks like ‘coffee grounds’
- bleeding into joints causing painful swelling

Some bleeding is common (affects less than 1 in 10 people). However, severe bleeding is uncommon (affects less than 1 in 100 people), but can be life threatening.

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.

TTP has been very rarely reported for patients treated with ticagrelor (frequency cannot be estimated from the available data).

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- tightness of the chest, wheezing, coughing or difficulty breathing.
- swelling of the face, lips, tongue or other parts of the body.
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin.
- Slow and/ or irregular heart rate.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Ticagrelor Sandoz. You may need urgent medical attention or hospitalisation.

The level of uric acid in your blood may increase while taking Ticagrelor Sandoz.

Your doctor may order blood tests to monitor the level of uric acid in your blood.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may get other side effects while taking Ticagrelor Sandoz.

Do not be concerned by this list of side effects. You may not get any of them. If you experience any side effects, do not stop taking Ticagrelor Sandoz until you have spoken with your doctor.

After using Ticagrelor Sandoz

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take Ticagrelor Sandoz out of the blister pack they may not keep well.

Keep it in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any Ticagrelor Sandoz tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What it looks like

Ticagrelor Sandoz 60 mg film-coated tablets

Round, biconvex, pink, film-coated tablets for oral use with "60" on one side and plain on the reverse.

Ticagrelor Sandoz 90 mg film-coated tablets

Round, biconvex, yellow, film-coated tablets for oral use with "90" on one side and plain on the reverse.

Available in blister packs of 56 tablets.

Ingredients

Active ingredient:

- ticagrelor 60 mg or 90 mg

In addition to ticagrelor each tablet contains:

- Mannitol
- Calcium hydrogen phosphate dihydrate
- Maize starch
- Starch, pregelatinised (Maize)
- Talc
- Poly(vinyl alcohol)
- Titanium dioxide
- Glycerol monocaprylocaprate
- Sodium laurilsulfate
- Iron oxide red (60 mg tablet only)
- Iron oxide black (60 mg tablet only)
- Iron oxide yellow (90 mg tablet only)

Supplier

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