TIRELA

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using TIRELA?

TIRELA contains the active ingredient ticagrelor. TIRELA is used to help stop the clumping of platelets, reduces the chance of a blood clot and reducing the chance of you having another heart attack, chest pain or stroke.

For more information, see Section 1. Why am I using TIRELA? in the full CMI.

2. What should I know before I use TIRELA?

Do not use if you have ever had an allergic reaction to ticagrelor or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use TIRELA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TIRELA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take TIRELA?

- The starting dose is two tablets at the same time. This dose will usually be given to you in the hospital. After that, the usual dose is one tablet twice a day.
- Take your doses at around the same time every day. For example, one in the morning and one in the evening. It does not matter whether you take TIRELA with food or on an empty stomach.
- If you have trouble swallowing, tablets may be crushed and mixed with water, or may be given via a nasogastric tube.

More instructions can be found in Section 4. How do I use TIRELA? in the full CMI.

5. What should I know while taking TIRELA?

Things you should do	• Take TIRELA exactly as the doctor has told you to. • Remind any doctor, dentist or pharmacist you visit that you are taking TIRELA. • Tell your doctor if you become pregnant while you are taking TIRELA. • Tell your doctor if you decide to breast feed your baby.
Things you should not do	• Do not stop using this medicine without talking to your doctor. Take it for as long as your doctor keeps prescribing it. If you want to stop taking TIRELA, talk to your doctor first.
Driving or using machines	• Be careful driving or operating machinery.
Drinking alcohol	• Check with your doctor first if you are intending to drink alcohol while taking TIRELA.
Looking after your medicine	• Keep your tablets in the blister pack until it is time to take them. • Keep it in a cool, dry place where the temperature stays below 30°C.

For more information, see Section 5. What should I know while using TIRELA? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may be serious and could require urgent medical attention or hospitalisation. If you notice signs of allergic reaction, stroke, bleeding or blood clots, contact your doctor or go to the Emergency Department of your nearest hospital immediately. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

TIRELA (TI-RE-LA)

Active ingredient(s): *Ticagrelor (tica-gre-lor)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TIRELA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TIRELA.**

Where to find information in this leaflet:

1. Why am I using TIRELA?
2. What should I know before I use TIRELA?
3. What if I am taking other medicines?
4. How do I use TIRELA?
5. What should I know while using TIRELA?
6. Are there any side effects?
7. Product details

1. Why am I taking TIRELA?

TIRELA contains the active ingredient ticagrelor. TIRELA belongs to a group of medicines called anti- platelet medicines.

Platelets 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')

TIRELA helps stop the clumping of platelets. This reduces the chance of a blood clot forming that can block a blood vessel. This means that TIRELA 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 TIRELA 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.

There is no evidence that TIRELA is addictive.

TIRELA is used because you have had:

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

2. What should I know before I take TIRELA?

Warnings

Do not take TIRELA 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, tightness of the chest, wheezing, coughing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body; rash, itching or hives.
- 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 TIRELA to treat any other complaint unless your doctor advises you to. Do not give this medicine to anyone else.

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

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

Check with your doctor, dentist or pharmacist if you:

- **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 TIRELA.**

  This is because of the increased risk of bleeding. Your doctor may want you to stop taking TIRELA for a short time.
- **you have or have had high uric acid.**
- **you have a low heart rate.**
- **you have or have had any medical conditions.**

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.
It is not recommended you take TIRELA. Your doctor will discuss the risks and benefits of taking TIRELA during pregnancy.

Tell your doctor if you are breast feeding or intend to breast feed.
It is not recommended you take TIRELA. Your doctor will discuss the risks and benefits of taking TIRELA during breast feeding.

Children

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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:

- rosuvastatin or more than 40 mg daily of simvastatin (medicine used to treat high cholesterol)
- rifampin (an antibiotic)
- phenytoin, carbamazepine phenobarbital (used to control seizures), dexamethasone (used to treat inflammatory and auto immune conditions)
- digoxin (used to treat heart failure)
- cyclosporin (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.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TIRELA.

They will have more information on medicines to be careful with or avoid while taking TIRELA.

4. How do I take TIRELA?

Follow all directions given to you by your doctor 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 starting dose is two tablets at the same time. This dose will usually be given to you in the hospital. After that, the usual dose is one tablet twice a day.

How to take TIRELA

Swallow each tablet whole with a drink of water.

If you have trouble swallowing TIRELA 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 it 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 in the tube into the stomach.

Your doctor will usually also tell you to take acetylsalicylic acid (aspirin). Your doctor will tell you how much to take (usually 100 mg but may vary between 75-150 mg).

It does not matter whether you take TIRELA with food or on an empty stomach.

Take your doses at around the same time every day. For example, one in the morning and one in the evening.

Taking your tablets at the same time each day will have the best effect. It will also help you to remember when to take it. You can check the day when you last took a TIRELA film-coated tablet by looking at days 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.

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

If you forget to take TIRELA

TIRELA should be used regularly at the same time each day. If you miss your dose at the usual time, take your next dose as normal.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

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

If you take too much TIRELA

If you think that you have used too much TIRELA, you may need urgent medical attention as you may be at increased risk of bleeding.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 1126**), or contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking TIRELA?

Things you should do

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

Things you should not do

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

  This is because the benefits of TIRELA are based on you taking it all the time. If you stop taking TIRELA 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.**
- **Do not take TIRELA to treat any other complaint unless your doctor advises you to.**

Driving or using machines

Be careful driving or operating machines or tools until you know how TIRELA affects you.

TIRELA 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.

Looking after your medicine

- **Keep it in a cool, dry place where the temperature stays below 30°C.**
- **Keep your tablets in the blister pack until it is time to take them.** If you take TIRELA out of the blister pack it will not keep well.

Follow the instructions in the carton on how to take care of your medicines properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• 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 TIRELA. 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. • Bruising • Nosebleed • Headache • Stomach pain • Constipation, diarrhoea or indigestion • Feeling of being sick • Rash • Inflamed stomach (gastritis) • A tingling feeling • Fainting • Slow and/or irregular heart rate • Signs of irregular breathing (central sleep apnoea and Cheyne-Stokes respiration). This has been reported in a small number of patients taking TIRELA (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.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
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:** • Blood in your urine. • Black stools or blood in your stools. • Bleeding after surgery or from cuts and wounds that is more than normal. 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 blood clotting, such as:** • Fever and purplish spots on the skin or in the mouth, with or without yellowing of the skin or eyes, unexplained extreme tiredness or confusion. **Signs of serious allergic reaction, such as:** • 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,	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

	redness, blistering or peeling of the skin.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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

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

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 TIRELA until you have spoken with your doctor.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

Each tablet contains ticagrelor 90 mg as the active ingredient.

This medicine is only available with a doctor's prescription.

What TIRELA contains

Active ingredient (main ingredient)	**Ticagrelor**
Other ingredients (inactive ingredients)	• Lactose monohydrate • Calcium hydrogen phosphate dihydrate • Microcrystalline cellulose • Hyprolose • Sodium starch glycolate type A • Magnesium stearate • Hypromellose • Titanium dioxide • Purified talc • Macrogol 400 • Iron oxide yellow • Purified water

Do not take this medicine if you are allergic to any of these ingredients.

What TIRELA looks like

TIRELA tablets are yellow coloured, round shaped biconvex, film coated tablets, debossed with '90' on one side and plain on the other side.

Aust R 426090.

Who distributes TIRELA

Nova Pharmaceuticals Australasia Pty Ltd
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Australia
Toll free: 1800 002 171

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