

# ARX-TICAGRELOR

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## 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.

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### 1. Why am I taking ARX-TICAGRELOR?

ARX-TICAGRELOR contains the active ingredient ticagrelor. ARX-TICAGRELOR is used for the prevention of heart attacks and unstable angina (angina or chest pain that is not well controlled).

For more information, see Section [1. Why am I taking ARX-TICAGRELOR?](#) in the full CMI.

### 2. What should I know before I take ARX-TICAGRELOR?

Do not use if you have ever had an allergic reaction to ARX-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 take ARX-TICAGRELOR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ARX-TICAGRELOR 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 ARX-TICAGRELOR?

- 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 ARX-TICAGRELOR with food or on an empty stomach.

More instructions can be found in Section [4. How do I take ARX-TICAGRELOR?](#) in the full CMI.

### 5. What should I know while taking ARX-TICAGRELOR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking ARX-TICAGRELOR.</li></ul>
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	<ul style="list-style-type: none"> <li>• Take ARX-TICAGRELOR exactly as your doctor has told you to.</li> <li>• Tell your doctor if you become pregnant while you are taking ARX-TICAGRELOR.</li> <li>• Tell your doctor if you decide to breast feed your baby.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop taking ARX-TICAGRELOR without talking to your doctor. Take it for as long as your doctor keeps prescribing it. If you want to stop taking ARX-TICAGRELOR, talk to your doctor first.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your tablets in the blister pack until it is time to take them.</li> <li>• Keep it in a cool, dry place where the temperature stays below 30°C.</li> </ul>

For more information, see Section [5. What should I know while taking ARX-TICAGRELOR?](#) 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. See Section [6. Are there any side effects?](#) in the full CMI and, if you need to, ask your doctor if you have any further questions about side effects.

# ARX-TICAGRELOR

Active ingredient: *ticagrelor*

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## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

- [1. Why am I taking ARX-TICAGRELOR?](#)
- [2. What should I know before I take ARX-TICAGRELOR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take ARX-TICAGRELOR?](#)
- [5. What should I know while taking ARX-TICAGRELOR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking ARX-TICAGRELOR?

**ARX-TICAGRELOR contains the active ingredient ticagrelor.** ARX-TICAGRELOR 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

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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').

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

**You have been given ARX-TICAGRELOR because you have had:**

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

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

ARX-TICAGRELOR is only available on a doctor's prescription.

There is no evidence that ARX-TICAGRELOR is addictive.

## **2. What should I know before I take ARX-TICAGRELOR?**

### **Warnings**

#### **Do not take ARX-TICAGRELOR if:**

- you are allergic to ticagrelor, or any of the ingredients listed at the end of this 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).

#### **Check with your doctor if you:**

- **have allergies to any other medicines, foods, preservatives, or dyes.**
- **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
- **have asthma or other lung problem or breathing difficulties.**
- **are due to have surgery (including dental work) at any time while taking ARX-TICAGRELOR.**

This is because of the increased risk of bleeding. Your doctor may want you to stop taking ARX-TICAGRELOR for a short time.

- **have or have had high uric acid.**
- **have a low heart rate.**
- **have or have had any medical conditions.**

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 that you take ARX-TICAGRELOR. Your doctor will discuss the risks and benefits of taking ARX-TICAGRELOR during pregnancy.



**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

It is not recommended that you take ARX-TICAGRELOR. Your doctor will discuss the risks and benefits of taking ARX-TICAGRELOR during breast feeding.

## **Children**

ARX-TICAGRELOR 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 (used to treat high cholesterol).
- rifampin (an antibiotic).
- phenytoin, carbamazepine and 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), often 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 ARX-TICAGRELOR.**

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

## **4. How do I take ARX-TICAGRELOR?**

**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.

### **ARX-TICAGRELOR film-coated tablets**

Swallow each tablet whole with a drink of water.

If you have trouble swallowing ARX-TICAGRELOR 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.

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 ARX-TICAGRELOR 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 ARX-TICAGRELOR 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.

## **How long to take it**

You should take ARX-TICAGRELOR for as long as your doctor tells you to.

## **If you forget to take ARX-TICAGRELOR**

ARX-TICAGRELOR 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. Then go back to taking it as you would normally.

**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 ARX-TICAGRELOR**

If you think that you have taken too much ARX-TICAGRELOR, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), 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.**

If you take too many ARX-TICAGRELOR tablets you may be at increased risk of bleeding.

## **5. What should I know while taking ARX-TICAGRELOR?**

### **Things you should do**

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

### **Things you should not do**

- **Do not stop taking ARX-TICAGRELOR without talking to your doctor. Take it for as long as your doctor keeps prescribing it. If you want to stop taking ARX-TICAGRELOR, talk to your doctor first.**  
This is because the benefits of ARX-TICAGRELOR are based on you taking it all the time. If you stop taking ARX-TICAGRELOR without talking to your doctor it

may increase the chance of a heart attack or stroke or a blood clot forming.

- **Do not take ARX-TICAGRELOR to treat any other complaint unless your doctor advises you to.**
- **Do not give this medicine to anyone else, even if they have symptoms that seem similar to yours.**

## **Driving or using machines**

### **Be careful driving or operating machinery.**

ARX-TICAGRELOR 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 your tablets in the blister pack until it is time to take them.**

If you take ARX-TICAGRELOR out of the blister pack it will not keep well.

Store it in a cool dry place below 30°C and 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.

Heat and dampness can destroy some medicines.

### **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

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

**Do not take 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.

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
<ul style="list-style-type: none"><li>• Feeling shortness of breath</li></ul> <p>This is very common (affects more than 1 in 10 people). It might be due to your heart disease or another cause, or it</p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>



<b>Less serious side effects</b>	<b>What to do</b>
<p data-bbox="199 250 730 757">might be a side effect of ARX-TICAGRELOR. 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.</p> <ul data-bbox="199 788 753 1933" style="list-style-type: none"> <li>● Bruising</li> <li>● Nosebleed</li> <li>● Headache</li> <li>● Stomach pain</li> <li>● Constipation, diarrhoea or indigestion</li> <li>● Feeling of being sick</li> <li>● Rash</li> <li>● Inflamed stomach (gastritis)</li> <li>● A tingling feeling</li> <li>● Fainting</li> <li>● Slow and/or irregular heart rate</li> <li>● Signs of irregular breathing (central sleep apnoea and Cheyne-Stokes respiration)</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<p>This has been reported in a small number of patients taking ticagrelor tablets (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.</p>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Signs of a stroke, such as:</b></p> <ul style="list-style-type: none"> <li>• sudden numbness or weakness of your arm, leg or face, especially if</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>only on one side of the body.</p> <ul style="list-style-type: none"> <li>● sudden confusion, difficulty speaking or understanding others.</li> <li>● sudden difficulty in walking or loss of balance or co-ordination.</li> <li>● suddenly feeling dizzy or sudden severe headache with no known cause.</li> </ul> <p><b>These are signs of a kind of stroke caused by bleeding into the brain. This is uncommon (affects less than 1 in 100 people).</b></p> <p><b>Signs of bleeding, including:</b></p> <ul style="list-style-type: none"> <li>● Blood in your urine.</li> <li>● Black stools or blood in your stools.</li> <li>● Bleeding after surgery or from cuts and wounds that is more than normal.</li> </ul>	<p><b>notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>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.</p> <p><b>Signs of blood clotting, such as:</b></p> <ul style="list-style-type: none"> <li>● 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.</li> </ul> <p><b>Signs of serious allergic reaction, such as:</b></p> <ul style="list-style-type: none"> <li>● tightness of the chest, wheezing, coughing or difficulty breathing.</li> <li>● swelling of the face, lips, tongue or other parts of the body.</li> <li>● severe skin reaction which may include rash, itching, redness,</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
blistering or peeling of the skin.	

**The level of uric acid in your blood may increase while taking ARX-TICAGRELOR.**

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

**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.

## **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](http://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**

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

# What ARX-TICAGRELOR contains

<p><b>Active ingredient (main ingredient)</b></p>	<p>Each tablet contains ticagrelor 90 mg as the active ingredient.</p>
<p><b>Other ingredients (inactive ingredients)</b></p>	<p><b>ARX-TICAGRELOR film-coated tablets</b></p> <ul style="list-style-type: none"> <li>• Mannitol</li> <li>• Calcium hydrogen phosphate dihydrate</li> <li>• Sodium starch glycollate</li> <li>• Hydroxypropylcellulose</li> <li>• Magnesium stearate</li> <li>• Hyprolose</li> <li>• Titanium dioxide</li> <li>• Purified talc</li> <li>• Macrogol 400</li> <li>• Iron oxide yellow</li> </ul> <p>ARX-TICAGRELOR does not contain gluten.</p>

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

## What ARX-TICAGRELOR looks like

### ARX-TICAGRELOR film-coated tablets

Round, biconvex, yellow, film-coated tablets for oral use with "90" above "T" on one side and plain on the reverse. Available in a blister pack of 56 tablets (AUST R 445790).

## **Who distributes ARX-TICAGRELOR**

AstraZeneca Pty Ltd

ABN 54 009 682 311

66 Talavera Road

MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

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