

# BRICALOR

TICAGRELOR TABLETS 90 MG

## 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 BRICALOR?

BRICALOR film-coated tablets contains the active ingredient Ticagrelor. BRICALOR is used to a heart attack, or unstable angina (angina or chest pain that is not well controlled). For more information, see Section [1. Why am I using BRICALOR?](#) in the full CMI.

### 2. What should I know before I use BRICALOR?

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

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

Some medicines may interfere with BRICALOR 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 use BRICALOR?

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. Swallow each tablet whole with a drink of water. If you have trouble swallowing BRICALOR film-coated tablets you BRICALOR® can crush them and mix with water. If you are using a nasogastric tube because you cannot swallow at all. More instructions can be found in Section [4. How do I use BRICALOR?](#) in the full CMI.

### 5. What should I know while using BRICALOR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using BRICALOR.</li><li>• Keep all of your doctor's appointments so that your progress can be checked. Your doctor will do regular tests (blood, urine or Magnetic Resonance Imaging (MRI)) to make sure the medicine is working and to prevent unwanted side effects. Your doctor will also use these tests to decide when you should stop taking BRICALOR.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking BRICALOR without talking to your doctor. Take it for as long as your doctor keeps prescribing it. If you want to stop taking BRICALOR, talk to your doctor first.</li><li>• Do not give this medicine to anyone else, even if they have symptoms that seem similar to yours.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• BRICALOR 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.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your medicine in the original container until it is time to take it.</li><li>• Store it in a cool, dry place, below 25°C.</li></ul>

For more information, see Section [5. What should I know while using BRICALOR?](#) in the full CMI.

## 6. Are there any side effects?

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 BRICALOR. 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 BRICALOR (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. 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.

**BRICALOR Active ingredient(s):** [*Ticagrelor*]

### Consumer Medicine Information (CMI)

This leaflet provides important information about using [BRICALOR]. **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 [BRICALOR].**

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

[1. Why am I using BRICALOR?](#)

[2. What should I know before I use BRICALOR?](#)

[3. What if I am taking other medicines?](#)

[4. How do I use BRICALOR?](#)

[5. What should I know while using BRICALOR?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

## 1. Why am I using BRICALOR?

**BRICALOR contains the active ingredient ticagrelor.**

BRICALOR 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').

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

BRICALOR is only available on a doctor's prescription.

There is no evidence that BRICALOR is addictive.

## 2. What should I know before I take BRICALOR?

### Warnings

**Do not take BRICALOR if:**

- You have an allergy to 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).

#### **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 BRICALOR.**

This is because of the increased risk of bleeding. Your doctor may want you to stop taking BRICALOR 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 you take you take BRICALOR. Your doctor will discuss the risks and benefits of taking BRICALOR during pregnancy.

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

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

#### **Children**

BRICALOR 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) 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 affects BRICALOR.**

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

#### **4. How do I take BRICALOR?**

**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.

##### **BRICALOR film-coated tablets**

Swallow each tablet whole with a drink of water.

If you have trouble swallowing BRICALOR 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.

##### **When to take BRICALOR**

**It does not matter whether you take BRICALOR 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 BRICALOR 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 BRICALOR for as long as your doctor tells you to.

##### **If you forget to take BRICALOR**

AKM 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 double the 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 AKM TICAGRELOR*

If you think that you have taken too much AKM TICAGRELOR, 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 BRICALOR tablets you may be at increased risk of bleeding.

## **5. What should I know while taking BRICALOR?**

### *Things you must do*

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

### *Things you should not do*

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

This is because the benefits of BRICALOR are based on you taking it all the time. If you stop

taking BRICALOR without talking to your doctor it may increase the chance of a heart attack or stroke or a blood clot forming.

- **Do not take AKM-TICAGREL 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.**

BRICALOR 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 AKM- 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 AKM-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>• A 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 other cause, or it might be a side effect of BRICALOR. 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 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> <p>This has been reported in a small number of patients taking BRICALOR (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</p>	

speeding up, slowing down or short pauses in breathing. Your doctor will decide if you need further evaluation.	
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### Serious side effects

Serious side effects	What to do
<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 only on one side of the body.</li> <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>These are signs of a kind of stroke caused by bleeding into the brain. This is uncommon (affects less than 1 in 100 people).</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>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>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.</b></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, blistering or peeling of the skin.</li> </ul>	
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**The level of uric acid in your blood may increase while taking BRICALOR.**

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.**

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.**

**After using it**

**Storage**

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

If you take BRICALOR out of the blister pack it will 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 windowsill or in the car on hot days.

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.

**Disposal**

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

**7. Product details**

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

**What BRICALOR contains:**

<p><b>Active ingredient (main ingredient)</b></p>	<p>Ticagrelor 90 mg</p>
<p><b>Other ingredients (inactive ingredients)</b></p>	<ul style="list-style-type: none"> <li>• Mannitol</li> <li>• Calcium hydrogen Phosphate Dihydrate</li> <li>• Croscarmellose sodium</li> <li>• Hyprollose</li> <li>• Magnesium stearate</li> <li>• Opadry complete film coating system 02B520003 yellow (111369)</li> <li>• PHARMACOR TICAGRELOR does not contain gluten.</li> </ul>

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

**What BRICALOR looks like**

BRICALOR are round, biconvex, light yellow to yellow, film coated tablet debossed with “90” on one side and “A” over “049” on other side.

BRICALOR 90 mg is available in calendar blisters (with sun/moon symbols) in cartons of 14, 28 and 56 tablets.

**Who distributes BRICALOR**

Pharmacor Australia Pty Ltd.  
Suite 803, Level 8 Tower A,  
The Zenith 821 Pacific Highway  
CHATSWOOD, NSW, 2067

[www.pharmacor.com.au](http://www.pharmacor.com.au)

**Australian Registration Number**

BRICALOR Tablets 90 mg  
AUST R 288019

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