

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 PIAX?

PIAX contains the active ingredient clopidogrel. PIAX is used to prevent blood clots forming in hardened blood vessels (a process known as thrombosis) which can lead to events such as stroke, heart attack or death.

For more information, see Section [1. Why am I using PIAX?](#) in the full CMI.

2. What should I know before I use PIAX?

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

3. What if I am taking other medicines?

Some medicines may interfere with PIAX 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 PIAX?

- Take PIAX only as prescribed by your doctor and follow his or her directions carefully.

More instructions can be found in Section [4. How do I use PIAX?](#) in the full CMI.

5. What should I know while using PIAX?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using PIAX. PIAX may increase the risk of bleeding during an operation or some dental work. • Tell your doctor immediately if you are injured while taking PIAX. It may take longer than usual to stop bleeding while you are taking PIAX. • Tell your doctor that you are taking PIAX if you are about to start on any new medicine.
Things you should not do	<ul style="list-style-type: none"> • Do not use PIAX during pregnancy or when you are breast feeding or intend to breast feed. • Do not stop using this medicine suddenly. • Do not take PIAX if you have a medical condition that is causing bleeding such as a stomach ulcer or bleeding within your head.
Driving or using machines	<ul style="list-style-type: none"> • PIAX may cause faintness or dizziness in some people. Make sure you know how you react to PIAX before you drive a car or operate machinery or do anything else that could be dangerous if you are faint or dizzy. If this occurs, do not drive.
Drinking alcohol	<ul style="list-style-type: none"> • PIAX may cause faintness or dizziness when taken with alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Keep PIAX in a cool, dry place where the temperature stays below 25°C. Store in original container.

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

6. Are there any side effects?

Like other medicines PIAX can cause some side effects. Most are likely to be minor and temporary. However, some may be serious and need medical attention such as bleeding or bruising more easily, blood in the urine and in the eye, coughing up blood, diarrhoea with blood, tightness of the chest, swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about using PIAX.

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 PIAX.

Where to find information in this leaflet:

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

1. Why am I using PIAX?

PIAX contains the active ingredient clopidogrel. Clopidogrel belongs to a group of medicines known as antiplatelet medicines.

Platelets are very small blood cells which clump together during blood clotting. By preventing this clumping, antiplatelet medicines reduce the chances of blood clots forming (a process called thrombosis)

PIAX is used to prevent blood clots forming in hardened blood vessels as they can lead to events such as stroke, heart attack or death.

You may have been prescribed PIAX to help prevent blood clots forming and to reduce the risk of stroke, heart attack and death because:

- you have previously suffered a heart attack, stroke or have a condition known as peripheral arterial disease (leg pain on walking or at rest).
- you have suffered Acute Coronary Syndrome (either a severe type of chest pain called unstable angina, or a heart attack). In this case you may also be prescribed aspirin.

Your doctor may have prescribed this medicine for another use. If you want more information, ask your doctor.

PIAX is only available on a doctor's prescription

2. What should I know before I use PIAX?

Warnings

Do not use PIAX if:

- you are allergic to any medicine containing clopidogrel
- you are allergic to any of the ingredients listed at the end of this 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 and rash, itching or hives on the skin

- you have a medical condition that is causing bleeding such as a stomach ulcer or bleeding within your head
- you suffer from severe liver disease

- if the packaging is torn or shows signs of tampering.
- If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- Have allergies to any medicines, foods, preservative or dyes.
- have any other medical conditions, especially the following
 - bleeding disorders or blood clotting problems
 - any illness or disability that was caused by bleeding for example impaired sight or vision because of bleeding within the eye
 - recent serious injury
 - recent surgery (including dental surgery)
 - liver or kidney problems
 - allergic to other antiplatelet medicines (such as ticlopidine, prasugrel).
 - rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption
- take any medicines for any other condition
- are planning to have an operation (including dental surgery) in the next two weeks. Your doctor will decide whether or not you need to stop PIAX prior to surgery

If you have not told your doctor about any of the above, tell him/her before you start taking PIAX.

Some patients may not convert PIAX to its active form as well as other patients. These patients may not get the same benefit from PIAX. Your doctor may advise you to go for tests to determine if PIAX will adequately work for you. Based on the test results, your doctor may change your dose of PIAX or consider alternative treatments for you.

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.

Your doctor will discuss the possible risks and benefits of taking PIAX during pregnancy

Talk to your doctor if you are breastfeeding or intend to breastfeed. PIAX passes into breast milk and, therefore, there is the possibility that the breast fed baby may be affected.

Use in Children

PIAX is not recommended for children because the safety and effectiveness of PIAX 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.

Some medicines may interfere with PIAX and affect how it works. These include:

- medicines that "thin the blood". The most common examples of these include aspirin, heparins and warfarin. There are other medicines used to 'thin the blood'.
Check with your doctor or pharmacist to see if any medicine you take may have this effect.
- non-steroidal anti-inflammatory drugs (NSAIDs) - medicines used to treat arthritis, period pain, aches and pains,
- medicines used to treat stomach ulcers or reflux disease (also called heartburn),
- Some medicines used to treat infections (e.g. ciprofloxacin, chloramphenicol, fluconazole and voriconazole),
- Some antidepressant medicines
- medicines used to treat epilepsy (e.g. carbamazepine, oxycarbazepine and phenytoin),
- medicines used to treat diabetes (e.g. tolbutamide, repaglinide),
- fluvastatin - a medicine used to lower cholesterol,
- medicines used to treat breast cancer (e.g. tamoxifen, paclitaxel),
- medicines used to prevent gastric reflux - proton pump inhibitors (e.g. omeprazole).
- Certain type of pain relief medicines called opiates.
- rosuvastatin (used to lower your cholesterol level)

These medicines may be affected by PIAX or affect how well PIAX works.

Your doctor may need to change the amount of your medicines, or you 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 PIAX.

4. How do I use PIAX?

How much to take / use

- Follow the instructions provided and use PIAX until your doctor tells you to stop. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

- The usual dose of PIAX is one 75 mg tablet daily.
- If you are prescribed PIAX for the treatment of Acute Coronary Syndrome, you may receive a starting dose of 300 mg (four 75 mg tablets), then one 75 mg tablet daily.

When to take / use PIAX

- You can take PIAX before or after meals. You should swallow the tablet with a glass of water.
- You should take PIAX for as long as your doctor continues to prescribe it. It is important to keep taking your medicine even if you feel well.

If you forget to use PIAX

PIAX should be used regularly at the same time each day. Taking your tablet at the same time each day will have the best effect. It will also help you to remember when to take the tablet.

If you miss a dose, take it as soon as you remember. 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 are not sure what to do, ask your doctor or pharmacist.
- If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much PIAX

If you think that you have used too much PIAX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 using PIAX?

Things you should do

Call your doctor straight away if you:

- if you become pregnant while taking PIAX
- if you decide to breast feed your baby. Your doctor may want to discuss this and change your medicine.
- if you are about to start on any new medicine
- if you are injured while taking PIAX. It may take longer than usual to stop bleeding while you are taking PIAX.
- if you notice any of the following:
 - abnormal bruising or bleeding;
 - abnormal nose bleeds;
 - red or purple blotches on your skin;
 - bloody or black bowel motions;
 - swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing (see also Side Effects section).

Take PIAX exactly as your doctor has prescribed, and have any blood tests promptly when your doctor recommends that tests be done.

Ask your doctor whether there are any activities you should avoid while taking PIAX, for example certain sports.

Sometimes after an injury bleeding may occur inside your body without you knowing about it.

Remind any doctor, dentist or pharmacist you visit that you are using PIAX. If you are going to have surgery, tell the surgeon. PIAX may increase the risk of bleeding during an operation or some dental work. Therefore, treatment may need to be stopped before surgery. Your doctor will decide whether to stop PIAX and if so, how long before surgery or dental work.

Things you should not do

There are activities you should avoid while taking PIAX, for example certain sports. Sometimes after an injury bleeding may occur inside your body without you knowing about it. Ask your doctor for advice.

- Do not stop using this medicine suddenly or change the dosage without checking with your doctor.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take PIAX to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PIAX affects you.

PIAX may cause faintness or dizziness in some people. Make sure you know how you react to PIAX before you drive a car operate machinery, or do anything else that could be dangerous if you are faint or dizzy. If this occurs do not drive.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol faintness or dizziness may be worse.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
- If you take your tablets out of the box or blister pack they will not keep well.

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

Store it in a cool dry place where the temperature stays below 25°C. Store in original container 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.

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid second-hand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).
- Be active. Progress, over time, to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-

angina medicine, carry it with you when being physically active.

- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

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
<p>General</p> <ul style="list-style-type: none">• things taste different• hunger• a fast, pounding heart beat <p>Gut-related</p> <ul style="list-style-type: none">• diarrhoea <p>Skin-related</p> <ul style="list-style-type: none">• itching• flushing <p>Nervous system-related</p> <ul style="list-style-type: none">• trembling <p>Joint-related</p> <ul style="list-style-type: none">• pain or stiffness in the joints	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Blood-related</p> <ul style="list-style-type: none">• anaemia (being tired and looking pale)• coughing up blood• blood in the urine• bleeding in eyes• unusually heavy bleeding or oozing from cuts or wounds• bleeding (including nose bleeds) or bruising more easily than normal	<p>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.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> unusually heavy or unexpected menstrual bleeding <p>Gut-related</p> <ul style="list-style-type: none"> bloody or black bowel motions diarrhoea with blood, mucus, stomach pain and fever abdominal or stomach pain vomiting of blood or vomit that looks like coffee grounds nausea or vomiting pale stools and dark urine with vomiting and stomach pain <p>Allergic-reaction</p> <ul style="list-style-type: none"> tightness of the chest, wheezing, coughing or difficulty breathing swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing 	<p>NOTE: If you take both PIAX and aspirin the risk of side effects related to bleeding may be increased.</p>

Serious side effects	What to do
<p>General</p> <ul style="list-style-type: none"> weight loss muscle weakness muscle pain breast enlargement in men fever or other signs of infection, such as a sore throat faintness or dizziness light-headedness or blurred vision loss of appetite and fatigue slurred speech or other difficulty in speaking headache (severe and continuing) <p>Skin-related</p> <ul style="list-style-type: none"> rash or hives red or purple spots visible through your skin itching, inflamed, cracking or red skin yellowing of the skin or the whites of the eyes chills, sweating or clammy skin <p>Nervous system-related</p> <ul style="list-style-type: none"> confusion or hallucinations numbness (paralysis) or problems with co-ordination 	<p>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.</p> <p>NOTE: If you take both PIAX and aspirin the risk of side effects related to bleeding may be increased.</p>

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. 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 PIAX contains

Active ingredient (main ingredient)	clopidogrel (as hydrogen sulfate) 75 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> magnesium stearate sodium lauryl sulfate colloidal anhydrous silica microcrystalline cellulose lactose croscarmellose sodium Opadry II complete film coating system 40C18303 white (ARTG PI No: 13191) Opadry complete film coating system YS-1-7006 Clear (ARTG PI No: 12789)
Potential allergens	PIAX contains sugars as lactose and trace quantities of sulfites

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

What PIAX looks like

PIAX film-coated tablets are white, film-coated, round, biconvex, beveled edge tablets debossed with "M" on one side of the tablet and "C27" on the other side. Blister packs of 28 tablets (AUST R 168927) and HDPE bottles of 280 tablets (hospital use only) (AUST R 168926).

Who distributes PIAX

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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