

Piax

clopidogrel (as hydrogen sulfate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Piax.

It does not contain all the available information. Some of the information it contains may not apply to you.

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

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

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

Keep this leaflet with your medicine.

You may need to read it again.

What Piax is used for

PIAX contains the medicine 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 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.

Before you take Piax

When you must not take it

Do not take 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
- you are breast feeding or intend to breast feed

Piax passes into breast milk and, therefore, there is the possibility that the breast fed baby may be affected.

Piax is not recommended for children because the safety and effectiveness of Piax in children have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

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 if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- 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).

Tell your doctor if you are pregnant or plan to become pregnant. Your doctor will discuss the possible risks and benefits of taking Piax during pregnancy.

Tell your doctor if you 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines and Piax may interfere with each other. These include:

- medicines that "thin the blood". The most common examples of these include aspirin, heparin 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.

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.

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 Piax.

How to take Piax

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

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.

How much to take

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.

How to take it

Swallow the tablets with a glass of water, before or after meals.

When to take it

Piax can be taken at any time of the day. However, your dose of Piax should be taken at about the same time each day.

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

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

It is important to keep taking your medicine even if you feel well.

If you forget to take it

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 take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Piax. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep the number of these facilities handy.

While you are taking Piax

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Piax.

Tell any other doctors, dentists, nurses and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

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.

If you become pregnant while taking this medicine or you decide to breast feed your baby, tell your doctor immediately.

Your doctor may want to discuss your decision and change your medicine.

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.

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 immediately 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).

Things you must 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 take Piax to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not suddenly stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Piax affects you.

As with other medicines 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.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol faintness or dizziness may be worse.

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.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list 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 if you notice any of the following and they worry you:

- diarrhoea
- itching
- pain or stiffness in the joints
- things taste different
- hunger
- trembling
- flushing
- a fast, pounding heart beat

Tell your doctor immediately if you notice any of the following:

(NOTE: If you take both Piax and aspirin the risk of side effects related to bleeding may be increased)

- bloody or black bowel motions
- diarrhoea with blood and mucus, stomach pain and fever
- abdominal or stomach pain
- nausea or vomiting
- vomiting of blood or vomit that looks like coffee grounds
- coughing up blood
- blood in the urine
- bleeding in eyes
- unusually heavy bleeding or oozing from cuts or wounds
- unusually heavy or unexpected menstrual bleeding
- breast enlargement in men
- bleeding (including nose bleeds) or bruising more easily than normal
- rash or hives
- itching, inflamed, cracking or red skin
- red or purple spots visible through your skin
- anaemia (being tired and looking pale)
- numbness (paralysis) or problems with co-ordination

- fever, muscle weakness, loss of appetite and fatigue
- muscle pain
- weight loss
- faintness or dizziness
- light-headedness or blurred vision
- confusion or hallucinations
- slurred speech or other difficulty in speaking
- tightness of the chest, wheezing, coughing or difficulty breathing
- headache (severe and continuing)
- fever or other signs of infection, such as a sore throat
- swelling of the face, lips, mouth tongue or throat which may cause difficulty in swallowing or breathing
- chills, sweating or clammy skin
- yellowing of the skin or whites of the eyes, vomiting, pale stools, dark urine with vomiting and stomach pain.

These could be more serious side effects - you may need urgent medical attention.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After taking Piax

Storage

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.

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

Heat and dampness can destroy some medicines. Do not leave Piax in the car on hot days.

Do not store Piax or any other medication in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Keep Piax 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

If your doctor tells you to stop taking Piax, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it 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.

Piax film-coated tablets are packaged in blister packs of 28 tablets and HDPE bottles of 280 tablets.

Ingredients

Each Piax film coated tablet contains the active ingredient: clopidogrel (as hydrogen sulfate) 75 mg

The inactive ingredients are:

- magnesium stearate
- sodium lauryl sulfate
- colloidal anhydrous silica
- microcrystalline cellulose
- lactose
- croscarmellose sodium
- Opadry II complete film coating system 40C18303 white (Proprietary Ingredient Number 13191) and
- Opadry complete film coating system YS-1-7006 Clear (Proprietary Ingredient Number 12789)

Piax contains sugars (as lactose) and trace quantities of galactose and sulfites.

Supplier

Piax is supplied by:

Alphapharm Pty Limited
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian registration numbers:

Piax Clopidogrel (as hydrogen sulfate) 75mg film-coated tablet blister pack - AUST R 168927

Piax Clopidogrel (as hydrogen sulfate) 75mg film-coated tablet bottle (hospital use only) - AUST R 168926

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