

Clopidogrel Winthrop® Tablets

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 Clopidogrel Winthrop?

Clopidogrel Winthrop contains the active ingredient clopidogrel. Clopidogrel Winthrop is used to prevent blood clots forming in hardened blood vessels (a process known as atherothrombosis) which can lead to events such as stroke, heart attack or death. For more information, see Section [1. Why am I using Clopidogrel Winthrop?](#) in the full CMI.

2. What should I know before I use Clopidogrel Winthrop?

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

3. What if I am taking other medicines?

Some medicines may interfere with Clopidogrel Winthrop 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 Clopidogrel Winthrop?

- Take Clopidogrel Winthrop 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 Clopidogrel Winthrop?](#) in the full CMI.

5. What should I know while using Clopidogrel Winthrop?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using Clopidogrel Winthrop. Clopidogrel Winthrop may increase the risk of bleeding during an operation or some dental work. - Tell your doctor immediately if you are injured while taking Clopidogrel Winthrop. It may take longer than usual to stop bleeding while you are taking Clopidogrel Winthrop. - Tell your doctor that you are taking Clopidogrel Winthrop if you are about to start on any new medicine.
Things you should not do	- Do not use Clopidogrel Winthrop during pregnancy. - Do not use Clopidogrel Winthrop if you are breast feeding or intend to breast feed. - Do not stop using this medicine suddenly. - Do not take Clopidogrel Winthrop if you have a medical condition that is causing bleeding such as a stomach ulcer or bleeding within your head.
Driving or using machines	Clopidogrel Winthrop may cause faintness or dizziness in some people. Make sure you know how you react to Clopidogrel Winthrop 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.
Looking after your medicine	Keep Clopidogrel Winthrop in a cool, dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Like other medicines Clopidogrel Winthrop 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.

Clopidogrel Winthrop® Tablets

Active ingredient: Clopidogrel (clop-id-o(h)-grel)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Clopidogrel Winthrop. **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 Clopidogrel Winthrop.**

Where to find information in this leaflet:

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

1. Why am I using Clopidogrel Winthrop?

Clopidogrel Winthrop contains the active ingredient **clopidogrel**. Clopidogrel Winthrop belongs to a group of medicines called **anti-platelet medicines**.

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

Clopidogrel Winthrop is used to prevent blood clots forming in hardened blood vessels (a process known as atherothrombosis) which can lead to events such as stroke, heart attack or death.

You may have been prescribed Clopidogrel Winthrop 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.

Clopidogrel Winthrop is only available on a doctor's prescription.

2. What should I know before I use Clopidogrel Winthrop?

Warnings

Do not use Clopidogrel Winthrop if:

- you are allergic to clopidogrel, or any of the ingredients listed at the end of this leaflet.
- 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.
- the packaging shows signs of tampering.
- the expiry date on the pack has passed. If you use this product after the expiry date has passed, it may not work.

Do not take Clopidogrel Winthrop to treat any other complaint unless your doctor says it is safe. Do not give this medicine to anyone else.

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - bleeding disorders or blood clotting problems
 - liver or kidney 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)
 - 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 Clopidogrel Winthrop prior to surgery

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

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

Do not use Clopidogrel Winthrop during pregnancy unless in the opinion of your doctor there is a clear need.

Your doctor will discuss the possible risks and benefits of taking Clopidogrel Winthrop during pregnancy.

Do not use Clopidogrel Winthrop if you are breast feeding or intend to breast feed. Clopidogrel Winthrop passes into breast milk and, therefore, there is the possibility that the breast fed baby may be affected.

Use in Children

Clopidogrel Winthrop is not recommended for children 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.

Some medicines may interfere with Clopidogrel Winthrop 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 others so please check with your doctor.
- 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 (eg ciprofloxacin, chloramphenicol, fluconazole and voriconazole)
- Some antidepressant medicines.
- medicines used to treat epilepsy (e.g. carbamazepine, oxcarbazepine and phenytoin)
- medicines used to treat diabetes (eg. tolbutamide, repaglinide)
- medicines used to treat breast cancer (e.g tamoxifen, paclitaxel)
- fluvastatin - a medicine used to lower cholesterol
- 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 Clopidogrel Winthrop or affect how well Clopidogrel Winthrop 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 Clopidogrel Winthrop.

4. How do I use Clopidogrel Winthrop?

How much to take

- Your doctor will tell you how many tablets to take each day. Take Clopidogrel Winthrop only as prescribed by your doctor and follow his or her directions carefully. They may differ from the information contained in this leaflet.
- The usual dose of Clopidogrel Winthrop is one 75 mg tablet daily.
- If you are prescribed Clopidogrel Winthrop 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 Clopidogrel Winthrop

- You can take Clopidogrel Winthrop before or after meals. You should swallow the tablet with a glass of water.
- You should take Clopidogrel Winthrop for as long as your doctor continues to prescribe it.

If you forget to use Clopidogrel Winthrop

Clopidogrel Winthrop 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 it.

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 to take your medicine, ask your pharmacist for some hints.

If you use too much Clopidogrel Winthrop

If you think that you have used too much Clopidogrel Winthrop, 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.

5. What should I know while using Clopidogrel Winthrop?

Things you should do

Call your doctor straight away if you:

- if you become pregnant while taking Clopidogrel Winthrop.
- 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 Clopidogrel Winthrop. It may take longer than usual to stop bleeding while you are taking Clopidogrel Winthrop.
- if you notice any of the following:
 - abnormal bruising or bleeding
 - abnormal nose bleeds
 - bloody or black bowel motions
 - red or purple blotches on your skin
 - swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing (see also 'Side effects' section)

Take Clopidogrel Winthrop exactly as your doctor has prescribed, and have any blood tests promptly if your doctor orders them.

Ask your doctor whether there are any activities you should avoid while taking Clopidogrel Winthrop, 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 Clopidogrel Winthrop. Clopidogrel Winthrop 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 Clopidogrel Winthrop and if so, how long before surgery or dental work.

Things you should not do

- Do not stop using this medicine suddenly without telling your doctor.

Driving or using machines

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

Clopidogrel Winthrop may cause faintness or dizziness in some people. Make sure you know how you react to Clopidogrel Winthrop 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. If you drink alcohol, faintness or dizziness may be worse.

Drinking alcohol

Tell your doctor if you drink alcohol.

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 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.

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
General • things taste different • hunger • a fast, pounding heart beat Gut-related • diarrhoea Skin-related • itching • flushing Nervous system-related • trembling Joint-related • pain or stiffness in the joints	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
Blood-related • anaemia (being tired and looking pale) • coughing up blood • blood in the urine • blood in the eyes	Call your doctor straight away, or go straight to the Emergency Department at your nearest

Serious side effects	What to do
- unusually heavy bleeding or oozing from cuts or wounds - bleeding (including nose bleeds) or bruising more easily than normal - unusually heavy or unexpected menstrual bleeding Gut-related - 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	hospital if you notice any of these serious side effects. NOTE: If you take both Clopidogrel Winthrop and aspirin the risk of side effects related to bleeding may be increased.

Serious side effects	What to do
Allergic-reaction - 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 General - 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) Skin-related - 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 Nervous system-related - confusion or hallucinations	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. NOTE: If you take both Clopidogrel Winthrop and aspirin the risk of side effects related to bleeding may be increased.

Serious side effects	What to do
numbness (paralysis) or problems with co-ordination	

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 Clopidogrel Winthrop contains

Active ingredient (main ingredient)	clopidogrel (75 mg)
Other ingredients (inactive ingredients)	mannitol macrogol 6000 microcrystalline cellulose hydrogenated castor oil hypolose carnauba wax OPADRY II complete film coating system 32K14834 Pink The coating contains lactose monohydrate

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

What Clopidogrel Winthrop looks like

Clopidogrel Winthrop 75mg tablets come as pink round tablets with '75' engraved on one side and '1171' on the other (AUST R 148947).

A box contains 28 tablets.

Who distributes Clopidogrel Winthrop

Distributed by:

sanofi-aventis australia pty ltd
International Tower 3, Level 23
300 Barangaroo Avenue
Sydney NSW 2000
Freecall: 1800 818 806
Email: medinfo.australia@sanofi.com

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