

# Clopidogrel Winthrop® Plus Aspirin

## 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 using Clopidogrel Winthrop Plus Aspirin?

Clopidogrel Winthrop Plus Aspirin contains the active ingredient clopidogrel and aspirin. Clopidogrel Winthrop Plus Aspirin 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 Plus Aspirin?](#) in the full CMI.

### 2. What should I know before I use Clopidogrel Winthrop Plus Aspirin?

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

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

Some medicines may interfere with Clopidogrel Winthrop Plus Aspirin 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 Plus Aspirin?**

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

### **5. What should I know while using Clopidogrel Winthrop Plus Aspirin?**

<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 Clopidogrel Winthrop Plus Aspirin</li><li>● Tell your doctor immediately if you are injured while taking</li></ul>
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	<p>Clopidogrel Winthrop Plus Aspirin</p> <ul style="list-style-type: none"> <li>• Tell your doctor that you are taking Clopidogrel Winthrop Plus Aspirin if you are about to start on any new medicine.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not use Clopidogrel Winthrop Plus Aspirin during pregnancy or if you are breast feeding or intend to breast feed.</li> <li>• Do not stop using this Clopidogrel Winthrop Plus Aspirin suddenly or if you have a medical condition that is causing bleeding such as a haemophilia, stomach ulcer or bleeding within your head or bowel.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• Clopidogrel Winthrop Plus Aspirin may cause faintness or dizziness in some people. Make sure you know how you react to Clopidogrel Winthrop Plus Aspirin before you drive a car or operate machinery or do anything else that</li> </ul>

	could be dangerous if you are faint or dizzy. If this occurs, do not drive.
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• The consumption of alcohol may affect how well Clopidogrel Winthrop Plus Aspirin works; it may increase blood loss and stomach irritation. Please ask your doctor for more information.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep Clopidogrel Winthrop Plus Aspirin in a cool, dry place where the temperature stays below 25°C.</li> </ul>

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

## 6. Are there any side effects?

Like other medicines Clopidogrel Winthrop Plus Aspirin can cause some side effects. Most are likely to be minor and temporary. However, some may be serious and need medical attention. There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur. 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 Plus Aspirin®

**Active ingredients:** *Clopidogrel (clop-id-o(h)-grel) and Aspirin (as-per-in)*

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## Consumer Medicine Information (CMI)

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

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

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

# 1. Why am I using Clopidogrel Winthrop Plus Aspirin?

**Clopidogrel Winthrop Plus Aspirin contains the active ingredient clopidogrel and aspirin. Clopidogrel Winthrop Plus Aspirin 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 Plus Aspirin 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 Plus Aspirin to help prevent blood clots forming and to reduce the risk of heart attack, stroke or death, because you have suffered a severe type of chest pain called unstable angina, or had a heart attack.

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

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

## **2. What should I know before I use Clopidogrel Winthrop Plus Aspirin?**

### **Warnings**

#### **Do not use Clopidogrel Winthrop Plus Aspirin if:**

- you are allergic to clopidogrel, aspirin, salicylates, anti-inflammatories (Non-Steroidal Anti-Inflammatory Drugs) or any of the ingredients listed under 'Product Description' at the end of this leaflet.  
Always check the ingredients to make sure you can use this medicine.
- you have a medical condition that is causing bleeding such as a haemophilia, stomach ulcer or bleeding within your head or bowel.
- you suffer from severe liver disease.
- you have asthma, rhinitis or nasal polyps.
- 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 Plus Aspirin 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:**

- you have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes
- take any medicines for any other condition

- 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)
  - any form of liver disease
  - any recent history of stroke
  - any form of kidney disease
  - history of stomach ulcers or other problems with your digestive system
  - inherited diseases causing galactose intolerance, glucose-galactose malabsorption
  - Lapp lactase deficiency
  - glucose-6-phosphate dehydrogenase (G6PD) deficiency
  - gout
  - asthma or allergies
  - allergic to other antiplatelet medicines (such as ticlopidine, prasugrel)
- 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 Clopidogrel Winthrop Plus Aspirin prior to surgery

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

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

**Do not use Clopidogrel Winthrop Plus Aspirin in the third trimester of pregnancy.**

It is recommended not to take this medicine during first and second trimesters of pregnancy. Taking clopidogrel plus aspirin may harm your unborn baby.

If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking clopidogrel plus aspirin. If you become pregnant while taking clopidogrel plus aspirin, consult your doctor immediately as it is recommended not to take clopidogrel plus aspirin while you are pregnant.

**Do not take Clopidogrel Winthrop Plus Aspirin if you are breast feeding or intend to breast feed.** Clopidogrel Winthrop Plus Aspirin passes into breast

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

## **Use in Children**

Clopidogrel Winthrop Plus Aspirin 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 Plus Aspirin and affect how it works.**

These include:

- aspirin - Clopidogrel Winthrop Plus Aspirin already contains aspirin. Taking additional aspirin is not recommended. Please check with your doctor first.
- clopidogrel - Clopidogrel Winthrop Plus Aspirin already contains clopidogrel. Taking additional clopidogrel is not recommended. Please check with your doctor first.
- medicines that "thin the blood". The most common examples of these include 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 such as ibuprofen.
- nicorandil - a medicine used to treat angina.

- steroids e.g., hydrocortisone.
- bupropion.
- diazepam.
- some gout medicines.
- some antidepressant medicines.
- antiretrovirals e.g. tenofovir.
- ciprofloxacin, chloramphenicol, fluconazole and voriconazole - medicines used to treat infections.
- varicella vaccine.
- methotrexate - a medicine used to treat cancer or arthritis.
- Acetazolamide - a medicine used to treat glaucoma.
- carbamazepine, oxcarbazepine, phenytoin and valproic acid - medicines used to treat epilepsy.
- tolbutamide, repaglinide and chlorpropamide - medicines used to treat diabetes.
- tamoxifen and paclitaxel medicines used to treat breast cancer.
- levothyroxine - a medicine used to treat low thyroid activity.
- fluvastatin - a medicine used to lower cholesterol.
- ACE inhibitors or angiotensin receptor antagonists plus a thiazide diuretic. These medicines are used to treat high blood pressure. In some cases the medicines may be used together to treat other cardiovascular diseases
- 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 Plus Aspirin or affect how well Clopidogrel Winthrop Plus Aspirin 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 Plus Aspirin.**

## **4. How do I use Clopidogrel Winthrop Plus Aspirin?**

### **How much to take**

**Clopidogrel Winthrop Plus Aspirin is to be used under medical supervision only.**

Your doctor will tell you how many tablets to take each day. Take Clopidogrel Winthrop Plus Aspirin 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 Plus Aspirin is one tablet daily.
- Clopidogrel Winthrop Plus Aspirin contains 75 mg clopidogrel and 100 mg aspirin

- You may receive a starting dose of 300 mg clopidogrel, then one Clopidogrel Winthrop Plus Aspirin tablet daily.

Take Clopidogrel Winthrop Plus Aspirin 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 to remember when to take it.

Should your doctor require you to take higher doses of aspirin you will be switched to separate tablets and no longer take Clopidogrel Winthrop Plus Aspirin.

Follow the instructions provided and use Clopidogrel Winthrop Plus Aspirin until your doctor tells you to stop.

## **When to take Clopidogrel Winthrop Plus Aspirin**

- Take Clopidogrel Winthrop Plus Aspirin during or immediately after a meal. You should swallow the tablet with a glass of water.
- You should take Clopidogrel Winthrop Plus Aspirin for as long as your doctor continues to prescribe it.

## **If you forget to use Clopidogrel Winthrop Plus Aspirin**

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.

**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 Plus Aspirin**

If you think that you have used too much Clopidogrel Winthrop Plus Aspirin, 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 Plus Aspirin?

### Things you should do

- take Clopidogrel Winthrop Plus Aspirin exactly as your doctor has prescribed, and have any blood tests promptly if your doctor orders them.
- tell your doctor if you become pregnant while taking Clopidogrel Winthrop Plus Aspirin.
- tell your doctor if you decide to breastfeed your baby. Your doctor may want to discuss this and change your medicine.
- tell your doctor that you are taking Clopidogrel Winthrop Plus Aspirin if you are about to start on any new medicine.
- tell all your doctors, dentists, nurses and pharmacists that you are taking Clopidogrel Winthrop Plus Aspirin. Clopidogrel Winthrop Plus Aspirin 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 Plus Aspirin and if so, how long before surgery or dental work.
- ask your doctor whether there are any activities you should avoid while taking Clopidogrel Winthrop Plus Aspirin, for example certain sports. Sometimes after an injury bleeding may occur inside your body without you knowing about it.

## **Call your doctor straight away if you:**

- if you are injured while taking Clopidogrel Winthrop Plus Aspirin.
- It may take longer than usual to stop bleeding while you are taking Clopidogrel Winthrop Plus Aspirin.
- 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)
  - symptoms or signs of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which may include flu-like symptoms and a rash with fever, enlarged lymph nodes and increase in a type of white blood cell (eosinophilia). Other abnormal blood test results may include (but are not limited to) increased levels of liver enzymes

## **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 Plus Aspirin affects you.**

Clopidogrel Winthrop Plus Aspirin may cause faintness or dizziness in some people. Make sure you know how you react to Clopidogrel Winthrop Plus Aspirin 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.**

The consumption of alcohol may affect how well Clopidogrel Winthrop Plus Aspirin works; it may increase blood loss and stomach irritation. Please ask your doctor for more information.

## **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.

Heat and dampness can destroy some medicines. Do not leave Clopidogrel Winthrop Plus Aspirin in the car on hot days.

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

## Serious side effects

Serious side effects	What to do
<p data-bbox="204 432 513 477"><b>Blood-related</b></p> <ul data-bbox="204 510 772 1368" style="list-style-type: none"><li data-bbox="204 510 692 622">● anaemia (being tired and looking pale)</li><li data-bbox="204 636 644 680">● coughing up blood</li><li data-bbox="204 703 619 748">● blood in the urine</li><li data-bbox="204 770 612 815">● blood in the eyes</li><li data-bbox="204 837 756 994">● unusually heavy bleeding or oozing from cuts or wounds</li><li data-bbox="204 1016 772 1173">● bleeding (including nose bleeds) or bruising more easily than normal</li><li data-bbox="204 1196 724 1368">● unusually heavy or unexpected menstrual bleeding</li></ul> <p data-bbox="204 1391 584 1435"><b>Allergic-reaction</b></p> <ul data-bbox="204 1469 778 1942" style="list-style-type: none"><li data-bbox="204 1469 735 1637">● tightness of the chest, wheezing, coughing or difficulty breathing</li><li data-bbox="204 1659 778 1942">● swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li></ul>	<p data-bbox="810 432 1378 822"><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>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● a severe reaction affecting the skin, blood and internal organs (DRESS)</li> </ul> <p><b>Gut-related</b></p> <ul style="list-style-type: none"> <li>● bloody or black bowel motions</li> <li>● diarrhoea with blood, mucus, stomach pain and fever</li> <li>● abdominal or stomach pain</li> <li>● vomiting of blood or vomit that looks like coffee grounds</li> <li>● nausea or vomiting</li> <li>● pale stools and dark urine with vomiting and stomach pain</li> </ul> <p><b>General</b></p> <ul style="list-style-type: none"> <li>● weight loss</li> <li>● headache (severe and continuing)</li> <li>● loss of appetite and fatigue</li> <li>● slurred speech or other difficulty in speaking</li> <li>● heartburn</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● breast enlargement in men</li> <li>● fever or other signs of infection, such as a sore throat</li> <li>● muscle weakness</li> <li>● muscle pain</li> <li>● faintness or dizziness</li> <li>● light-headedness or blurred vision</li> <li>● buildup of fluid in the body that can cause swelling (oedema)</li> </ul> <p><b>Skin-related</b></p> <ul style="list-style-type: none"> <li>● rash or hives</li> <li>● red or purple spots visible through your skin</li> <li>● itching, inflamed, cracking or red skin</li> <li>● yellowing of the skin or the whites of the eyes</li> <li>● chills, sweating or clammy skin</li> </ul> <p><b>Nervous system-related</b></p> <ul style="list-style-type: none"> <li>● confusion or hallucinations</li> </ul>	



<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• numbness (paralysis) or problems with co-ordination</li> </ul>	

**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 Clopidogrel Winthrop Plus Aspirin contains

<b>Active ingredient (main ingredient)</b>	Clopidogrel Winthrop Plus Aspirin 75mg/100mg: clopidogrel 75 mg, aspirin 100 mg
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• mannitol</li><li>• carnauba wax</li><li>• macrogol 6000</li><li>• microcrystalline cellulose</li><li>• hydrogenated castor oil</li><li>• hypromellose</li><li>• maize starch</li><li>• stearic acid</li><li>• colloidal anhydrous silica</li><li>• lactose monohydrate</li><li>• OPADRY II complete film coating system 32K24375 Pink</li></ul>

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

## **What Clopidogrel Winthrop Plus Aspirin looks like**

Clopidogrel Winthrop Plus Aspirin is available as:

Clopidogrel Winthrop Plus Aspirin 75mg/100mg tablets: light pink, oval tablets with 'C75' on one side and 'A100' on the other.

AUST R 150470.

Supplied in a box containing 30 tablets.

## **Who distributes Clopidogrel Winthrop Plus Aspirin**

Clopidogrel Winthrop Plus Aspirin is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Rd,

Macquarie Park NSW 2113

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