

CLOPIDOGREL RBX TABLETS

Clopidogrel hydrogen sulfate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CLOPIDOGREL RBX tablets.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have benefits and risks. In deciding to give you CLOPIDOGREL RBX, your doctor has weighed the risks of you taking CLOPIDOGREL RBX against the benefits it is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What CLOPIDOGREL RBX is used for

CLOPIDOGREL RBX contains the medicine clopidogrel. Clopidogrel 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 RBX 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 RBX 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.**

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another use.

CLOPIDOGREL RBX is only available on a doctor's prescription.

Before you use CLOPIDOGREL RBX

When you must not use it

You should not take CLOPIDOGREL RBX if:

- **you are allergic to clopidogrel or any of the ingredients listed under 'Product Description' 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.**
- **you are breast-feeding or intend to breast-feed. CLOPIDOGREL RBX passes into**

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

- **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 RBX to treat any other complaint unless your doctor tells you to. Do not give this medicine to anyone else.

CLOPIDOGREL RBX is not recommended for children as its safety and effectiveness in children have not been established.

Before you start to take CLOPIDOGREL RBX

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

You must tell your doctor if:

- **You are pregnant or intend to become pregnant.** Your doctor will discuss the possible risks and benefits of taking CLOPIDOGREL RBX during pregnancy.
- **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 RBX prior to surgery.
- **If you have or have had any 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
 - allergic to other antiplatelet medicines (such as ticlopidine, prasugrel)

Tell your doctor if you are lactose-intolerant. CLOPIDOGREL RBX contains lactose. If you think that you have intolerance to some sugars, tell your doctor before taking this medicine.

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

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

- medicines that "thin the blood". The most common examples of these include aspirin, heparins and warfarin. There are others so 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).
- phenytoin - a medicine used to treat epilepsy (fits).
- tolbutamide - a medicine used to treat diabetes (sugar diabetes).
- tamoxifen - a medicine used to treat breast cancer.
- fluvastatin - a medicine used to lower cholesterol.
- medicines used to prevent gastric reflux - proton pump inhibitors (e.g. omeprazole).

These medicines may be affected by CLOPIDOGREL RBX or affect how well CLOPIDOGREL RBX 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 CLOPIDOGREL RBX.

HOW to use CLOPIDOGREL RBX

How to take it

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

These may differ from the information contained in this leaflet.

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

The usual dose of CLOPIDOGREL RBX is one 75 mg tablet daily.

If you are prescribed CLOPIDOGREL RBX for the treatment of Acute Coronary syndrome, you may receive a starting dose of 300 mg (either one 300 mg tablet or four 75 mg tablets), then one 75 mg tablet daily.

You can take CLOPIDOGREL RBX before or after meals. You should swallow the tablet whole with a glass of water. **Take CLOPIDOGREL RBX 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.

You should take CLOPIDOGREL RBX for as long as your doctor tells you to.

If you forget to take CLOPIDOGREL RBX

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. This may increase the chance of you getting an unwanted side effect.

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to the Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much CLOPIDOGREL RBX. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking CLOPIDOGREL RBX

Things you must do

- Take **CLOPIDOGREL RBX** 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 RBX**.
- Tell your doctor if you decide to breast-feed your baby. Your doctor may want to discuss this and change your medicine.
- While you are taking **CLOPIDOGREL RBX**, tell your doctor or pharmacist before you start any new medicine.
- Tell all your doctors, dentists, nurses and pharmacists who are treating you that you are taking **CLOPIDOGREL RBX**. **CLOPIDOGREL RBX** 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 RBX** and if so, how long before surgery or dental work.
- Ask your doctor whether there are any activities you should avoid while taking **CLOPIDOGREL RBX**, 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 **CLOPIDOGREL RBX**. It may take longer than usual to stop bleeding while you are taking **CLOPIDOGREL RBX**.
- Tell your doctor immediately 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)

Do not suddenly stop taking **CLOPIDOGREL RBX** without telling your doctor.

Things to be careful of

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

As with other medicines, **CLOPIDOGREL RBX** may cause faintness or dizziness in some people. Make sure you know how you react to **CLOPIDOGREL RBX** 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.

Side Effects

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

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

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
- things taste differently
- pain or stiffness of the joints

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

(NOTE: If you take both **CLOPIDOGREL RBX** and aspirin, the risk of side effects related to bleeding may be increased).

- 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
- coughing up blood
- blood in the urine
- blood in the eyes
- 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
- numbness (paralysis) or problems with co-ordination
- nausea or vomiting
- faintness or dizziness
- light-headedness or blurred vision
- slurred speech or other difficulty in speaking
- headache (severe and continuing)
- confusion or hallucinations
- fever or other signs of infection, such as a sore throat
- rash or hives
- chills, sweating or clammy skin
- fever, muscle weakness, loss of appetite and fatigue
- muscle pain
- weight loss
- anaemia (being tired and looking pale)
- red or purple spots visible through your skin
- itching, inflamed, cracking or red skin
- tightness of the chest, wheezing, coughing or difficulty breathing
- yellowing of the skin or the whites of the eyes, pale stools and dark urine with vomiting and stomach pain
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

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

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

Do not be alarmed by this list of side effects. You may not experience any of them.

After using CLOPIDOGREL RBX

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 **CLOPIDOGREL RBX** in a cool, dry place where the temperature stays below 25 degrees C. Heat and dampness can destroy some medicines. Do not leave **CLOPIDOGREL RBX** in the car on hot days.

Do not store **CLOPIDOGREL RBX** or any other medication in the bathroom or near a sink.

Keep **CLOPIDOGREL RBX** 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 **CLOPIDOGREL RBX**, ask your pharmacist what to do with any tablets that are left over.

Product description

What CLOPIDOGREL RBX looks like

CLOPIDOGREL RBX 75 mg tablets are pink, round, film-coated tablets with 'C4' marked on one side and plain on the other side. Available in blister packs of 28 tablets.

Ingredients

Active ingredient:

CLOPIDOGREL RBX 75 mg tablets - clopidogrel 75 mg (as hydrogen sulfate)

Inactive ingredients:

- Lactose
- Microcrystalline cellulose
- Hydroxypropylcellulose
- Macrogol 6000
- Hydrogenated castor oil
- Hypromellose
- Titanium dioxide
- Macrogol 400
- Iron oxide red CI77491.

Sponsor

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