

Arrow - Clopidogrel

Clopidogrel Tablets 75mg

What is in this leaflet

This leaflet answers some common questions about ARROW - CLOPIDOGREL.

It does not contain all of the available information. 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 ARROW - CLOPIDOGREL 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 ARROW - CLOPIDOGREL is used for

ARROW - 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).

ARROW - CLOPIDOGREL is used to prevent blood clots from 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 ARROW – CLOPIDOGREL 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 in 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 ARROW - CLOPIDOGREL for another reason. Ask your doctor if you have any questions about why ARROW - CLOPIDOGREL has been prescribed for you.

ARROW - CLOPIDOGREL is available only with a doctor's prescription.

There is no evidence that ARROW - CLOPIDOGREL is addictive.

Before you take ARROW - CLOPIDOGREL

When you must not take it

Do not take ARROW - CLOPIDOGREL if you are allergic to medicines containing clopidogrel or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take ARROW - CLOPIDOGREL if you have:

- a medical condition that is causing bleeding such as stomach ulcers or bleeding within your head
- severe liver disease.

Do not take ARROW - CLOPIDOGREL if you are pregnant or planning to become pregnant.

ARROW - CLOPIDOGREL may affect your developing baby if you take it during pregnancy.

Do not take ARROW - CLOPIDOGREL if you are breastfeeding.

ARROW - CLOPIDOGREL passes into breast milk and may affect your baby.

Do not take ARROW - CLOPIDOGREL if the expiry date (Exp.) printed on the pack has passed.

Do not take ARROW - CLOPIDOGREL if the packaging is torn or shows signs of tampering.

ARROW - CLOPIDOGREL is not recommended for use in children under the age of 18, as its safety and effectiveness in children have not been established.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you plan to become pregnant or breastfeed.

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

- bleeding disorder, blood clotting problems
- any illness or disability caused by bleeding, e.g. impaired vision because of bleeding within the eye
- recent serious injury
- recent surgery (including dental surgery)
- kidney problems
- any form of liver disease.

Tell your doctor if you plan to have operation (including dental surgery) in the next two weeks your doctor will decide, whether or not you stop ARROW – CLOPIDOGREL prior to surgery.

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

Taking other medicines

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

Some medicines may be affected by ARROW - CLOPIDOGREL, or may affect how well it works. These include:

- medicines that thin the blood, e.g. aspirin, ticlopidine, heparins and warfarin
- non-steroidal anti-inflammatory drugs, medicines used to treat arthritis, period pain, aches and pains

- phenytoin or felbamate, medicines used to treat epilepsy
- tolbutamide, medicine used to treat diabetes
- tamoxifen, medicine used to treat breast cancer
- fluvastatin, medicine used to treat high cholesterol
- medicines which suppress the production of stomach acid eg. omeprazole, esomeprazole, lansoprazole, pantoprazole and cimetidine.
- anti-fungal medicines including fluconazole, ketoconazole and voriconazole.
- fluoxetine or fluvoxamine, used to treat depression and/or anxiety.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ARROW – CLOPIDOGREL.

How to take ARROW - CLOPIDOGREL

How much to take

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medicines.

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

If you are prescribed ARROW – CLOPIDOGREL for the treatment of Acute Coronary Syndrome, you will receive a starting dose of 300 mg (four 75 mg tablets), then one 75 mg tablet daily.

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

How to take ARROW - CLOPIDOGREL

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

If you forget to take ARROW - CLOPIDOGREL

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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 take too much ARROW - CLOPIDOGREL (overdose)

Immediately telephone your doctor, or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to the Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ARROW - CLOPIDOGREL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking ARROW - CLOPIDOGREL

Things you must do

Take ARROW – CLOPIDOGREL exactly as your doctor has prescribed, and have any blood tests promptly if your doctor orders them.

If you become pregnant or plan to become pregnant while taking ARROW - CLOPIDOGREL, tell your doctor.

Tell your doctor if you decide to breastfeed your baby. Your doctor may want to discuss this and change your medicine.

Before starting any new medicine, tell your doctor or pharmacist that you are taking ARROW - CLOPIDOGREL.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARROW - CLOPIDOGREL.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking ARROW - CLOPIDOGREL. ARROW – CLOPIDOGREL 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 ARROW – CLOPIDOGREL and if so, how long before surgery or dental work.

Ask your doctor whether there are any activities you should avoid while taking ARROW – CLOPIDOGREL, for example certain sports. Sometimes after an injury bleeding may occur inside your body without your knowing about it.

Tell your doctor immediately if you are injured while taking ARROW - CLOPIDOGREL.

It may take longer than usual to stop bleeding while you are taking ARROW – CLOPIDOGREL.

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).

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not stop taking ARROW - CLOPIDOGREL, or lower the dose, without checking with your doctor.

Do not use ARROW - CLOPIDOGREL to treat any other conditions unless your doctor tells you to.

Do not give ARROW - CLOPIDOGREL to anyone else, even if they have the same condition as you.

Things to be careful of

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

ARROW - CLOPIDOGREL may cause faintness, dizziness or light-headedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while taking ARROW - CLOPIDOGREL. Combining ARROW - CLOPIDOGREL and alcohol can make faintness or dizziness worse.

Side effects

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

Like all other medicines, ARROW - CLOPIDOGREL may have unwanted side effects in some people. 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 this list of possible 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 of the joints
- taste disturbances

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

- 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 nosebleeds) 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 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.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using ARROW - CLOPIDOGREL

Storage

Keep ARROW - CLOPIDOGREL where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the container until it is time to take them.

If you take the tablets out of the container, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25 °C.

Do not store ARROW - CLOPIDOGREL or any other medicine in the bathroom or near a sink.

Do not leave ARROW - CLOPIDOGREL in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ARROW - CLOPIDOGREL, ask your pharmacist what to do with any that are left over.

Product Description

What ARROW - CLOPIDOGREL looks like

Arrow - Clopidogrel is a pink, round biconvex tablet, with 'CP' on one side and 'S' on other side. Each tablet contains 75 mg of clopidogrel.

Ingredients

The active ingredient in ARROW - CLOPIDOGREL is clopidogrel. Each ARROW - CLOPIDOGREL tablet contains 75mg of clopidogrel.

Arrow - Clopidogrel tablets also contain the following excipients: propylene glycol (macrogol 6000), mannitol, microcrystalline cellulose, low substituted hydroxypropylcellulose, hydrogenated vegetable oil, red 30 iron oxide and Opadry II pink 39F94168 (contains lactose).

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrow Pharmaceuticals (NZ) Limited
Mount Eden Central Business Park
33a Normanby Road, Mt Eden
Auckland, New Zealand.

Date of preparation

04 November 2011