

PLAVIX[®] TABLET

Clopidogrel 75mg & 300mg

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What Plavix is used for

Plavix is taken to prevent blood clots (thrombi) forming in hardened blood vessels (arteries), a process known as atherothrombosis, which can lead to atherothrombotic events (such as stroke, heart attack, or death).

You have been prescribed Plavix to help prevent blood clots and reduce the risk of these severe events because:

- You have a condition of hardening of arteries (also known as atherosclerosis), and
- You have previously experienced a heart attack, stroke or have a condition known as peripheral arterial disease, or
- You have experienced a severe type of chest pain known as 'unstable angina' or 'myocardial infarction' (heart attack). For the treatment of this condition your doctor may have placed a stent in the blocked or narrowed artery to restore effective blood flow. You should also be given acetylsalicylic acid (a substance present in many medicines used to relieve pain and lower fever as well as to prevent blood clotting) by your doctor.

Indication only applicable to Plavix 75mg

- You have an irregular heartbeat, a condition called 'atrial fibrillation', and you cannot take medicines known as 'oral anticoagulants' (vitamin K antagonists) which prevent new clots from forming and prevent existing clots from growing.

You should have been told that 'oral anticoagulants' are more effective than acetylsalicylic acid or the combined use of Plavix and acetylsalicylic acid for this condition. Your doctor should have prescribed Plavix plus acetylsalicylic acid if you cannot take 'oral anticoagulants' and you do not have a risk of major bleeding.

How Plavix works

Plavix belongs to a group of medicines called antiplatelet medicinal products.

Platelets are very small structures in the blood, which clump together during blood clotting. By preventing this clumping, antiplatelet medicinal products reduce the chances of blood clots forming (a process called thrombosis).

Before you use Plavix

When you must not use it

Do not take Plavix:

- If you are allergic (hypersensitive) to clopidogrel or any of the other ingredients of Plavix;
- If you have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding within the brain;
- If you suffer from severe liver disease.

If you think any of these apply to you, or if you are in any doubt at all, consult your doctor before taking Plavix.

Before you start to use it

Take special care with Plavix

If any of the situations mentioned below apply to you, you should tell your doctor before taking Plavix:

- if you have a risk of bleeding such as
 - a medical condition that puts you at risk of internal bleeding (such as a stomach ulcer)
 - a blood disorder that makes you prone to internal bleeding (bleeding inside any tissues, organs or joints of your body).

- a recent serious injury
- a recent surgery (including dental)
- a planned surgery (including dental) in the next seven days

- if you have had a clot in an artery of your brain (ischaemic stroke) which occurred within the last seven days
- if you have kidney or liver disease

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including

medicines obtained without a prescription.

Some other medicines may influence the use of Plavix or vice versa.

You should specifically tell your doctor if you take

- oral anticoagulants, medicines used to reduce blood clotting,
- a non-steroidal anti-inflammatory medicine, usually used to treat painful and/or inflammatory conditions of muscle or joints,
- heparin or any other injectable medicine used to reduce blood clotting,
- omeprazole, esomeprazole or cimetidine, medicines to treat upset stomach
- fluconazole, voriconazole, ciprofloxacin, or chloramphenicol, medicines to treat bacterial and fungal infections,
- fluoxetine, fluvoxamine, or moclobemide, medicines to treat depression,
- carbamazepine, or oxcarbazepine, medicines to treat some forms of epilepsy,
- ticlopidine, other antiplatelet agent.

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed Plavix in combination with acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever. An occasional use of acetylsalicylic acid (no more than 1,000 mg in any 24 hour period) should generally not cause a problem, but prolonged use in other

circumstances should be discussed with your doctor.

Pregnancy and breast-feeding

- It is preferable not to take this product during pregnancy.
- If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking Plavix. If you become pregnant while taking Plavix, consult your doctor immediately as it is recommended not to take clopidogrel while you are pregnant.
- You should not breast-feed while taking this medicine.
- If you are breast-feeding or planning to breast-feed, talk to your doctor before taking this medicine.
- Ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of Plavix:

Plavix contains lactose. If you have been told by your doctor that you have intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine. Plavix also contains hydrogenated castor oil which may cause stomach upset or diarrhea.

How to use Plavix

Always take Plavix exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to use

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

These directions may differ from the information contained in this leaflet.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

If you have experienced severe chest pain (unstable angina or heart attack),

your doctor may give you 300 mg of Plavix (1 tablet of 300 mg or 4 tablets of 75 mg) once at the start of treatment. Then, the usual dose is one 75-mg tablet of Plavix per day.

When to use it

Plavix is to be taken orally with or without food, and at the same time each day.

How long to use it

Continue taking your medicine for as long as your doctor continues to prescribe it.

Please talk to your doctor before you consider stopping treatment.

If you forget to use it

If you forget to take a dose of Plavix, but remember within 12 hours of your usual time, take your tablet straightaway and then take your next tablet at the usual time.

If you forget for more than 12 hours, simply take the next single dose at the usual time.

Do not take a double dose to make up for the forgotten individual doses.

For the 7, 14, 28 and 84 tablets pack sizes, you can check the day on which you last took a tablet of Plavix by referring to the calendar printed on the blister.

If you use too much (overdose)

Contact your doctor or the nearest hospital emergency department because of the increased risk of bleeding.

While you are using it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Plavix.

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

- You should tell your doctor if a surgery (including dental) is planned.

- You should also tell your doctor immediately if you develop a medical condition (also known as Thrombotic Thrombocytopenic Purpura or TTP) that includes fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice) (see section 'SIDE EFFECTS').

- If you cut or injure yourself, it may take longer than usual for bleeding to stop. This is linked to the way your medicine works as it prevents the ability of blood clots to form. For minor cuts and injuries e.g., cutting yourself, shaving, this is usually of no concern. However, if you are concerned by your bleeding, you should contact your doctor straightaway (see section 'SIDE EFFECTS').

- Your doctor may order blood tests. Plavix is not intended for use in children or adolescents.

Things you must not do

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

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Plavix, or change the dosage, without checking with your doctor.

Things to be careful of **Driving and using machines**

Plavix is unlikely to affect your ability to drive or to use machines.

Side Effect

Like all medicines, Plavix can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:

- very common

(affects more than 1 user in 10)

- common

(affects 1 to 10 users in 100)

- uncommon

(affects 1 to 10 users in 1,000)

- rare

(affects 1 to 10 users in 10,000)

- very rare

(affects less than 1 user in 10,000)

- not known

(frequency cannot be estimated from the available data)

Contact your doctor immediately if you experience:

- fever, signs of infection or extreme tiredness. These may be due to rare decrease of some blood cells.

- signs of liver problems such as yellowing of the skin and/or the eyes (jaundice), whether or not associated with bleeding which appears under the skin as red pinpoint dots and/or confusion (see 'Take special care with Plavix').

- swelling in the mouth or skin disorders such as rashes and itching, blisters of the skin. These may be the signs of an allergic reaction.

The most common side effect reported with Plavix is bleeding.

Bleeding may occur as bleeding in the stomach or bowels, bruising, haematoma (unusual bleeding or bruising under the skin), nose bleed, blood in the urine.

In a small number of cases, bleeding in the eye, inside the head, the lung or the joints has also been reported.

Other side effects reported with Plavix are:

Common side effects: Diarrhoea, abdominal pain, indigestion or heartburn.

Uncommon side effects: Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, rashes, itching, dizziness, sensation of tingling and numbness.

Rare side effect: Vertigo.

Very rare side effects: Jaundice; fever, breathing difficulties sometimes associated with cough; generalised allergic reactions; swelling in the mouth; blisters of the skin; skin allergy; inflammation of the mouth (stomatitis); decrease in blood pressure; confusion; hallucinations; joint pain; muscular pain; changes in the way things taste.

In addition, your doctor may identify changes in your blood or urine test results.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Plavix

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

- Keep out of the reach and sight of children.

- Do not use Plavix after the expiry date which is stated on the carton and on the blister, after EXP.

- Store between 15°C and 30°C

Do not use Plavix if you notice any visible sign of deterioration.

Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Plavix 75mg film-coated tablets are round, biconvex, pink, engraved on one side with the number '75' and on the other side with the number '1171'.

Plavix is supplied in cardboard cartons containing 14 film-coated tablets in all aluminium blisters.

Plavix 300mg film-coated tablets are pink, oblong, engraved with '300' on one side and '1332' on the other side.

Plavix is supplied in cardboard cartons containing 4, 10 or 30 film-coated tablets in all aluminium blisters (Not all pack sizes may be marketed).

Ingredients:

The active substance is clopidogrel. Each 75mg tablet contains 75 mg of clopidogrel (as hydrogen sulphate). Each 300mg tablet contains 300 mg of Clopidogrel (as hydrogen sulphate).

The other ingredients are:

Core:

Mannitol (E421)

Macrogol 6000

Microcrystalline cellulose

Hydrogenated castor oil

Low substituted

hydroxypropylcellulose

Coating:

Hypromellose (E464)

Lactose monohydrate

Triacetin (E1518)

Titanium dioxide (E171)

Red iron oxide (E172)

Polishing agent:

Carnauba wax

MAL Numbers:

Plavix 75mg Film-coated Tablet:

MAL19992344A

Plavix 300mg Film-coated Tablet:

MAL10100020A

Manufacturer and Product Registration Holder

Manufacturer

Sanofi Winthrop Industrie

1, rue de la Vierge

Ambares et Lagrave

33565 Carbon Clanc Cedex

France

Product Registration Holder

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