

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

PLAVIX® 75 mg Film-coated tablets

Clopidogrel

Read all of this leaflet carefully before you start taking PLAVIX.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PLAVIX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT PLAVIX CONTAINS:

The active substance is clopidogrel.

Each film-coated tablet contains clopidogrel hydrogen sulphate (form II) equivalent to 75 mg of the clopidogrel base.

The other inactive ingredients are mannitol (sugar), hydrogenated castor oil, microcrystalline cellulose, macrogol 6000 and low-substituted hydroxypropylcellulose in the tablet core, and lactose (milk sugar), hypromellose, triacetin, red iron oxide (E172), titanium dioxide (E171) and carnauba wax in the tablet coating.

WHAT PLAVIX IS USED FOR:

You have been prescribed PLAVIX to help prevent blood clots and reduce the risk of these 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). In this case 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.

BEFORE YOU TAKE PLAVIX:

Do not take PLAVIX:

- if you are hypersensitive (allergic) to the active ingredient clopidogrel or to any of the other ingredients of PLAVIX.
- if you are hypersensitive (allergic) to other anti-platelet medicines called thienopyridine (such as ticlopidine, prasugrel), used to prevent blood clots.
- 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 are pregnant or breastfeeding.
- If you suffer from a dysfunction of, or reduction in, blood platelets which increases risk of bleeding and bruising.

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

PLAVIX is not intended for use in children or adolescents less than 18 years of age.

If you are pregnant or breastfeeding your baby while taking PLAVIX, please consult your doctor, pharmacist or other healthcare professional for advice.

Take special care with PLAVIX:

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

- If you have a risk of haemorrhage (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 tissue, 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.
 - a planned spinal, epidural anaesthetic or a lumbar puncture in the next seven days.
- If you have had a clot in an artery of your brain (ischaemic stroke) which occurred in the last seven days.
- If you have kidney or liver disease.
- If you are taking any other type of medication (see Taking other medicines with PLAVIX).

You should tell your doctor and anaesthetist that you take PLAVIX:

- if surgery (including dental) is planned.
- if you have any stomach or abdominal pain or bleeding in the stomach or bowels (red stools or black stools).

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 POSSIBLE 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 POSSIBLE SIDE EFFECTS). Your doctor may order blood tests.

Use in children:

PLAVIX is not intended for use in children or adolescents less than 18 years of age (see Do not take PLAVIX).

Taking PLAVIX with food and drink:

PLAVIX may be taken with or without food.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machines:

PLAVIX should not affect your ability to drive or to use machines.

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 PLAVIX.

PLAVIX also contains hydrogenated castor oil which may cause stomach upset or diarrhoea.

Taking other medicines with PLAVIX:

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

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

If you are taking other medicines on a regular basis, including medicines obtained without a prescription, traditional and complementary medicines, concomitant use of PLAVIX may cause undesirable interactions. Please consult your doctor, pharmacist or healthcare professional, for advice.

You should tell your doctor if you take:

- oral anticoagulants (such as warfarin), medicines used to reduce blood clotting,
- aspirin or non-steroidal anti-inflammatory medicines 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,
- a selective serotonin reuptake inhibitors (including but not restricted to fluoxetine or fluvoxamine), medicines usually used to treat depression
- ticlopidine or other antiplatelet medicines used to reduce blood clotting
- repaglinide, medicine to treat diabetes

- paclitaxel, medicine to treat cancer

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. Contact your doctor before using other aspirin containing medicines concomitantly with PLAVIX.

HOW TO TAKE PLAVIX:

Always take PLAVIX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share PLAVIX prescribed for you with others.

The usual dose is one 75 mg tablet of PLAVIX 75 mg per day to be taken orally with a glass of water, with or without food.

You should take your medicine regularly and at the same time each day.

Duration of treatment:

You should take PLAVIX for as long as your doctor continues to prescribe it.

If you take more PLAVIX than you should:

In the event of overdosage, immediately consult your doctor or pharmacist because of the increased risk of bleeding. If neither is available, rush the patient to the nearest hospital or poison control centre.

If you forget to take PLAVIX:

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 dose.

If you stop taking PLAVIX:

Do not stop the treatment unless your doctor tells you so. Contact your doctor or pharmacist before stopping.

If you have been told by your doctor to stop treatment temporarily, ask your doctor when to restart the treatment.

If you have any further questions on the use of PLAVIX, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS:

PLAVIX can have side effects.

Contact your doctor immediately if you experience:

- fever, signs of infection or extreme tiredness. These may be due to a decrease of some blood cells.
- signs of liver problems such as yellowing of the skin and/or 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 frequent side effect which has been seen 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.

If you experience prolonged bleeding when taking PLAVIX:

If you cut or injure yourself, it may take slightly longer than usual for bleeding to stop. This is linked to the way PLAVIX 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 Take special care with PLAVIX).

Other side effects which have been seen with PLAVIX are:

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

Less frequent side effects: Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, rashes, itching, dizziness, sensation of tingling and numbness; vertigo; enlarged breasts in males, jaundice; severe abdominal pain with or without back pain; 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, inflammation of small vessels.

Side effects with frequency not known (frequency cannot be estimated from the available data):

Hypersensitivity reactions with chest or abdominal pain.

Your doctor may identify changes in your blood or urine tests.

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

Not all side effects reported for PLAVIX are included in this leaflet. Should your general health worsen while taking PLAVIX, please consult your doctor, pharmacist or other healthcare professional for advice.

STORAGE AND DISPOSING OF PLAVIX:

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Store below 25 °C and protect from light. Do not remove blisters from the carton until required.

Do not use PLAVIX after the expiry date stated on the carton and on the blister.

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

Return all unused tablets to your pharmacist for safe disposal.

PRESENTATION OF PLAVIX:

28 tablets packed in PVC/PVDC or all aluminium blister strips in cardboard cartons.

IDENTIFICATION OF PLAVIX:

PLAVIX 75 mg tablets are pink, round, slightly biconvex, film-coated tablets engraved with «75» on one side and «1171» on the other side.

REGISTRATION NUMBER:

36/8.2/0408

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

sanofi-aventis south africa (pty) ltd.

2 Bond Street

Midrand

1685

South Africa

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