**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

The medicine is dispensed with a doctor's prescription only

**Plavix 75 mg** film-coated tablets

**Active ingredient**

Each Plavix 75 mg tablet contains: clopidogrel (as hydrogen sulfate) 75 mg

For information on inactive ingredients and allergens in the preparation, see section 2 - "Important information about some of the ingredients of the medicine" and section 6 - "Further information".

**Read this leaflet carefully in its entirety before using this medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

**1. What is the medicine intended for?**

The medicine is used for secondary prevention of atherothrombotic events in blood vessels (heart attacks, strokes or vascular death) in patients with atherosclerosis who have had a myocardial infarction, ischemic stroke, or who suffer from peripheral artery disease, and in patients suffering from unstable angina pectoris, including patients undergoing stent implantation in angioplasty and who are treated with aspirin.

The medicine is used for the prevention of atherothrombotic and thromboembolic events (heart attacks, strokes, emboli or vascular death) in combination with aspirin, in patients suffering from an irregular heart rhythm called atrial fibrillation who are not suitable for treatment with vitamin K antagonists such as warfarin (Coumadin), antithrombin or anti-factor Xa.

**Therapeutic group:** Platelet aggregation inhibitors, from the thienopyridine group.

**2. Before using the medicine**

| **Do not use the medicine if:**   * you are sensitive (allergic) to clopidogrel or any of the other ingredients the medicine contains (see section 6). * you are suffering from a medical condition that is currently causing bleeding such as a stomach or duodenal ulcer, intracranial bleeding. * you are suffering from severe liver disease.   If any of these apply to you, or if you have any doubt, consult your doctor before taking Plavix. |
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**Special warnings regarding use of the medicine:**

**Before treatment with the medicine tell the doctor 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).
  + you have recently suffered a serious injury.
  + you have recently undergone surgery (including dental).
  + you are due to undergo surgery (including dental) in the next seven days.
* you have suffered a clot in an artery of your brain (ischemic stroke) in the last seven days.
* you are suffering from kidney or liver disease.
* you have suffered in the past from an allergy or reaction to any medicine used to treat your disease.

**During treatment with the medicine:**

* You must tell your doctor if surgery (including dental) is planned.
* You must 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 4 "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 2 "Special warnings regarding use of the medicine").
* Your doctor may order blood tests.

**Children and adolescents**

This medicine is not intended for children and adolescents under 18 years of age.

**Drug interactions:**

**If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

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

You should specifically tell the doctor if you are taking:

* Medicines that may increase your risk of bleeding such as:
* oral anticoagulants, medicines used to reduce blood clotting,
* a non-steroidal anti-inflammatory medicine (NSAIDs), usually used to treat painful and/or inflammatory conditions of muscles or joints,
* heparin or any other injectable medicine used to reduce blood clotting,
* ticlopidine, or other antiplatelet agents,
* a selective serotonin reuptake inhibitor (SSRIs) (including but not restricted to fluoxetine or fluvoxamine), medicines usually used to treat depression,
* rifampicin (used to treat severe infections)
* omeprazole or esomeprazole, medicines to treat stomach upset,
* fluconazole or voriconazole, medicines to treat fungal infections,
* efavirenz, or other anti-retroviral medicines (used to treat HIV infection),
* carbamazepine, a medicine to treat some forms of epilepsy,
* moclobemide, medicine to treat depression,
* repaglinide, medicine to treat diabetes,
* paclitaxel, medicine to treat cancer,
* opioids: while you are treated with clopidogrel, you should inform your doctor before being prescribed any opioid medicine (used to treat severe pain),
* rosuvastatin (used to lower your cholesterol level).

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.

**Use of the medicine and food**

The medicine can be taken with or without food.

**Pregnancy, breastfeeding and fertility**

It is preferable not to take this medicine during pregnancy.

If you are pregnant or suspect that you are pregnant, you should tell your doctor or pharmacist before taking Plavix. If you become pregnant during treatment with the medicine, consult your doctor immediately as it is recommended not to take clopidogrel while you are pregnant.

You should not breastfeed while taking this medicine.

If you are breastfeeding or planning to breastfeed, talk to your doctor before taking this medicine.

Consult with your doctor or pharmacist before taking any medicine.

**Driving and using machines**

Plavix is not expected to affect your ability to drive or operate machines.

**Important information about some of the ingredients of the medicine**

**Plavix contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars (such as lactose), contact your doctor before taking this medicine.

**Plavix contains hydrogenated castor oil**

This may cause stomach upset or diarrhea.

**3. How should you use the medicine?**

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage, including for patients with a condition called "atrial fibrillation" (irregular heart rhythm), is: one tablet of Plavix 75 mg per day, taken orally, with or without food and at the same time each day.

If you have experienced severe chest pain (unstable angina or heart attack), your doctor may instruct you to take a one-time dose of 300 mg (4 tablets of 75 mg) at the start of treatment. Then, the recommended dosage is one tablet of Plavix 75 mg per day taken as described above.

**Do not exceed the recommended dose.**

You should take Plavix for as long as your doctor prescribes it.

There is no information regarding crushing or grinding the tablet.

Do not chew! Swallow the medicine with water. The medicine can be taken with or without food.

**If you accidentally took a higher dosage:**

Refer immediately to a doctor or to a hospital emergency room because of the increased risk of bleeding.

If an overdose has been taken or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

**If you forgot to take the medicine:**

If you forgot to take the Plavix dose but remember within 12 hours of the scheduled time, take the tablet immediately and then take the next tablet at the usual time.

If you forgot and more than 12 hours have passed, simply take the next single dose at the regular time. Do not take a double dose to make up for a forgotten tablet.

**Adhere to the treatment as recommended by the doctor.**

**If you stop taking Plavix:**

**Do not stop treatment unless instructed to do so by your doctor.** Refer to the doctor or pharmacist before stopping treatment.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

**4. Side effects**

As with any medicine, use of Plavix may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Consult with the doctor immediately if the following signs appear:**

* 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 eyes (jaundice), whether or not associated with bleeding which appears under the skin as red pinpoint dots, and/or confusion (see section 2 "Special warnings regarding use of the medicine").
* 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, hematoma (unusual bleeding or bruising under the skin), nosebleed, or 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 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 2 "Special warnings regarding use of the medicine").

**Other side effects include:**

Common side effects (may affect up to 1 in 10 people):

Diarrhea, abdominal pain, indigestion or heartburn.

Uncommon side effects (may affect up to 1 in 100 people):

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

Rare side effects (may affect up to 1 in 1,000 people):

Vertigo, enlarged breasts in males.

Very rare side effects (may affect up to 1 in 10,000 people):

Jaundice; severe abdominal pain with or without back pain; fever, breathing difficulties sometimes associated with cough; generalised allergic reactions (for example, overall sensation of heat with sudden general discomfort until fainting); swelling in the mouth; blisters of the skin; skin allergy; sore mouth (stomatitis); decrease in blood pressure; confusion; hallucinations; joint pain; muscular pain; changes in taste or loss of taste of food.

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

Hypersensitivity reactions with chest or abdominal pain, persistent low blood sugar symptoms.

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

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

**Reporting side effects:**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

**5. How should the medicine be stored?**

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

**Storage conditions:**

Store below 25°C.

Do not use the medicine if you notice any visible changes in the tablet.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Further information**

In addition to the active ingredient, the medicine also contains:

Mannitol, macrogol 6000, microcrystalline cellulose, low-substituted hydroxypropylcellulose, hydrogenated castor oil.

Tablet coating:

Lactose monohydrate, hypromellose, titanium dioxide, triacetin, red iron oxide, carnauba wax.

What the medicine looks like and the contents of the package:

Plavix 75 mg tablets are round, pink, film-coated tablets. On one side the number "75" is engraved and on the other side the number "1171" is engraved.

The package contains 30 tablets in a blister pack.

**This leaflet does not contain all the information about the preparation. If you have any question or are unsure about something, please refer to the doctor.**

**Registration holder and importer name and address:** Sanofi Israel Ltd., Gvat Shemesh St., P.O.B. 47, Yoqneam.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 110-70-29307-00

For simplicity and ease of reading, this leaflet was formulated in the masculine. However, the medicine is intended for both sexes.

Revised in December 2022 according to MOH guidelines.