

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

This 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 about inactive ingredients and allergens in the medicine, see section 2 under "Important information about some of the medicine's ingredients" and section 6 "Additional information".

**Read this leaflet carefully in its entirety before using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your 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 this medicine intended for?**

The medicine is intended for secondary prevention of atherothrombotic vascular events (heart attacks, cerebral stroke or vascular death) in patients with atherosclerosis who had a myocardial infarction, ischemic cerebrovascular event, or who suffer from peripheral arterial disease, and in patients suffering from unstable angina pectoris, including patients undergoing implant of a stent by catheterization and who are being treated with aspirin. The medicine is intended for prevention of atherothrombotic and thromboembolic events (heart attacks, cerebral stroke, emboli or vascular death) in combination with aspirin, in patients suffering from heart rhythm disorder such as atrial fibrillation, who are not suitable for treatment with anti-coagulants of the vitamin K antagonist type such as warfarin (Coumadin), anti-thrombin or anti-factor Xa.

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

### **2. Before using this medicine**

#### **Do not use this medicine if:**

- you are sensitive (allergic) to clopidogrel or to any of the other ingredients of this medicine (see section 6).
  - you suffer from a medical condition that is currently causing bleeding such as stomach or duodenal ulcer or bleeding within the brain.
  - you suffer from severe liver disease.
- If any of these apply to you, or if you are in any doubt at all, consult your doctor before taking Plavix.

#### **Special warnings regarding use of this medicine:**

##### **Before treatment with this 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 had a recent serious injury.
  - you had a recent surgery (including dental surgeries).
  - you are expected to undergo a surgery (including dental surgeries) in the next seven days.
- you have had a clot in an artery of your brain (ischemic stroke) which occurred within the last seven days.
- you have kidney or liver disease.
- you have had an allergy or reaction to any medicine used to treat your disease.

##### **During treatment with this medicine:**

- You should tell your doctor if a surgery (including dental surgery) is planned for you.
- 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 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 while shaving, this is usually of no concern. However, if you are concerned by the bleeding, you should contact your doctor straightaway (see section 4 "Side effects").

- Your doctor may order blood tests.

### **Children and adolescents**

This medicine is not intended for children and adolescents below the age of 18.

### **Drug interactions:**

**If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.**

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

You should specifically tell your doctor if you take:

- medicines that may increase your risk of bleeding such as:

- o oral anticoagulants, medicines used to reduce blood clotting,
- o non-steroidal anti-inflammatory drugs (NSAIDs), usually used to treat pain and/or inflammation of muscles or joints,
- o heparin or any other injectable medicine used to reduce blood clotting,
- o ticlopidine, other antiplatelet agent,
- o selective serotonin reuptake inhibitors (SSRIs), (including, but not restricted to, fluoxetine or fluvoxamine), medicines usually used to treat depression,
- o rifampicin (used to treat severe infections)
- omeprazole or esomeprazole, medicines to treat upset stomach,
- 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, a medicine to treat depression,
- repaglinide, a medicine to treat diabetes,
- paclitaxel, a medicine to treat cancer,
- opioids: while you are treated with clopidogrel, you should inform your doctor before being prescribed any opioid (used to treat severe pain).

If you have experienced severe chest pain (unstable angina pectoris 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 may be taken with or without food.

### **Pregnancy, breast-feeding 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 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, consult your doctor before taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

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

### **Important information about some of the medicine's ingredients**

#### **Plavix contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars (e.g. 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 medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

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

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

#### **You must exceed the recommended dosage.**

You must take Plavix for as long as your doctor continues to prescribe it for you.

There is no information regarding crushing the tablet.

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

#### **If you have accidentally taken a higher dosage:**

Immediately refer to a doctor or the nearest hospital emergency room because of the increased risk of bleeding.

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

#### **If you forget to take the medicine:**

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

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

#### **If you stop taking Plavix:**

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

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

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

## **4. Side effects**

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

#### **Consult 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 problem 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 section 2 "Special warnings regarding use of this medicine").
- swelling in the mouth or skin disorders such as rash, itching and 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), nose bleed, or blood in the urine. In a small number of cases, bleeding in the eye, inside the head, the lungs 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 while shaving, this is usually of no concern. However, if you are concerned by the bleeding, you should contact your doctor straightaway (see section 2 "Special warnings regarding use of this medicine").

#### **Additional side effects include:**

Common side effects (may affect up to 1 in 10 users):  
Diarrhoea, abdominal pain, indigestion or heartburn.

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

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

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

Vertigo, enlarged breasts in males.

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

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

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

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

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

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

#### **Reporting side effects:**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects, or by using this link:

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

## **5. How to store the medicine?**

Prevent poisoning! This medicine and any other medicines should be kept in a closed 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 a doctor.

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

#### **Storage conditions:**

Store at a temperature below 25°C.

Do not use this 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. Additional information**

In addition to the active ingredient, this medicine also contains: Mannitol, macrogol 6000, microcrystalline cellulose, low-substituted hydroxypropylcellulose, hydrogenated castor oil.

In the tablet coating:

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

What the medicine looks like and contents of the pack:

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

The package contains 30 tablets in a blister pack.

**This leaflet does not contain all the information about the medicine. If you have any question or are not sure about anything, please contact a doctor.**

**Marketing authorization holder's name and address:** Sanofi-Aventis Israel Ltd., 10 Beni Gaon St., POB 8090 Netanya 4250499.

**Manufacturer's name and address:** Sanofi Winthrop Industries, France.

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