



# Plavitor 75 mg film-coated tablets

*Clopidogrel*

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you have any side effects, including any side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

## What is in this leaflet?

1. What Plavitor is and what it is used for
2. What you need to know before you take Plavitor
3. How to take Plavitor
4. Possible side effects
5. How to store Plavitor
6. Contents of the pack and other information

### 1. What Plavitor is and what it is used for

Plavitor contains clopidogrel and belongs to a group of medicines called antiplatelet medicinal products. Platelets are very small structural elements of the blood which clump together during blood clotting. By preventing this clumping, antiplatelet medicinal products reduce the chances of blood clot formation (a process called thrombosis).

Plavitor is prescribed to adult patients 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).

Plavitor has been prescribed for you to 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
- previously experienced a heart attack, stroke or have a condition known as peripheral arterial disease, or
- 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.
- 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 know that oral anticoagulants are more effective than acetylsalicylic acid or the combined use of Plavitor and acetylsalicylic acid for this condition. Your doctor should prescribe Plavitor plus acetylsalicylic acid if you cannot take oral anticoagulants and if there is no risk of massive bleeding for you.

### 2. What you need to know before you take Plavitor

#### Do not take Plavitor

- if you are allergic to clopidogrel or any of the other ingredients of this medicine (listed in section 6);
- if you have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding in the brain;
- if you suffer from severe liver disease.

If you think any of these apply to you, or if you are in doubt at all, ask your doctor for advice before taking Plavitor.

#### Warnings and precautions

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

- have a risk of bleeding such as a

- medical condition associated with a risk of internal bleeding (such as a stomach ulcer);
- blood disorder that makes you susceptible to internal bleeding (bleeding inside tissues, organs or joints of your body);
- recent serious injury;
- recent surgery (including dental);
- planned surgery (including dental) in the next seven days;
- have had a clot in a brain artery (ischaemic stroke) within the last seven days;
- have kidney or liver disease;
- have had allergy or reaction to any medicine used to treat your disease.

While you are taking Plavitor:

- 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 hemorrhages 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 “Possible side effects”);
- If you cut or injure yourself, it may take longer than usual for the bleeding to stop. This is linked to the way your medicine works to prevent blood clot formation, and is usually of no concern for minor cuts and injuries, e.g. cutting yourself while shaving. However, if you are concerned by the bleeding, you should immediately contact your doctor (see section 4 “Possible side effects”);
- Your doctor may order blood tests.

#### Children and adolescents

Plavitor is not recommended for children or adolescents below 18 years old.

#### Other medicines and Plavitor

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including non-prescription ones.

Some other medicines may influence the use of Plavitor 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 usually used to treat painful and/or inflammatory conditions of muscles or joints;
  - o heparin or any other injectable medicine used to reduce blood clotting;
  - o ticlopidine, another antiplatelet agent;
  - o a selective serotonin reuptake inhibitor (including but not limited to fluoxetine or fluvoxamine), medicines usually used to treat depression;
- omeprazole or esomeprazole, medicines used to treat upset stomach;
- fluconazole or voriconazole, medicines used to treat fungal infections,
- efavirenz, a medicine used to treat HIV (human immunodeficiency virus) infections;
- 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.

If you have experienced a severe chest pain (unstable angina or heart attack), you may be prescribed Plavitor in combination with acetylsalicylic acid, a substance contained in many medicines used to relieve pain and reduce fever. An occasional use of acetylsalicylic acid (no more than 1 000 mg in 24-hours)

should generally not cause a problem, however prolonged use in other circumstances should be discussed with your doctor.

### **Plavivor with food and drink**

Plavivor may be taken with or without food.

### **Pregnancy, breast-feeding and fertility**

It is preferable not to take this medicinal product during pregnancy.

If you are pregnant or think you may be pregnant, you should tell your doctor or your pharmacist before taking Plavivor. If you become pregnant while taking Plavivor, consult your doctor immediately as it is recommended not to take clopidogrel during pregnancy.

You should not breastfeed while taking this medicine. If you are breastfeeding or planning to breastfeed, talk to your doctor before taking this medicine.

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

### **Driving and using machines**

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

### **3. How to take Plavivor**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose, including for patients with a condition called "atrial fibrillation" (an irregular heartbeat), is one 75 mg tablet of Plavivor daily to be taken orally with or without food, at the same time each day.

If you have experienced a severe chest pain (unstable angina or heart attack), your doctor may prescribe you 300 mg Plavivor (4 tablets of 75 mg) as a single dose at the start of treatment. Afterwards, the usual dose is one 75 mg tablet Plavivor daily taken orally with or without food, at the same time each day.

You should take Plavivor for as long as your doctor has prescribed it.

### **If you take more Plavivor than you should**

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

### **If you forget to take Plavivor**

If you forget to take a dose of Plavivor but remember it 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 a forgotten tablet.

### **If you stop taking Plavivor**

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

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

### **4. Possible side effects**

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

#### **Contact your doctor immediately if you experience:**

- fever, signs of infection or extreme tiredness. These may be due to a rare disease affecting 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 "Warnings and precautions");
- swelling of the mouth or skin disorders such as rashes and itching, blisters of the skin. These may be signs of an allergic reaction.

### **The most common side effect reported with Plavivor is bleeding.**

Bleeding may occur as bleeding from the stomach or intestines, bruising, haematoma (unusual bleeding or bruising under the skin), nose bleed, blood in the urine. In a small number of cases, bleeding in the eyes, inside the head, the lung or the joints has also been reported.

### **If you experience prolonged bleeding when taking Plavivor**

If you cut or injure yourself, it may take longer than usual for the bleeding to stop. This is linked to the way the medicine works to prevent blood clot formation, and is usually of no concern for minor cuts and injuries, e.g. cutting yourself while shaving. However, if you are concerned by the bleeding, you should immediately tell your doctor (see section 2 "Warnings and precautions").

### **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 the stomach or intestines, rashes, itching, vertigo, sensation of tingling and numbness.

Rare side effects (may affect up to 1 in 1000 people): vertigo, enlarged breasts in males.

Very rare side effects (may affect up to 1 in 10000 people): jaundice; severe abdominal pain with or without back pain; fever, difficulty breathing sometimes associated with cough; generalised allergic reactions (e.g. overall sensation of body warming with sudden general discomfort until fainting); swelling of the mouth; blisters of the skin; allergic skin reaction; inflammation of the mouth (stomatitis); blood pressure lowering; confusion; hallucinations; joint pain; muscle pain; changes in the taste of food.

Side effects with frequency not known (frequency cannot be estimated from the available data): hypersensitivity reactions with chest or abdominal pain.

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

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Plavivor**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack after "EXP".

Do not store above 30°C.

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. Contents of the pack and other information**

#### **What Plavivor contains**

The active substance is clopidogrel as bisulphate. Each tablet contains 75 mg clopidogrel.

The other ingredients are:

- Tablet core: mannitol, microcrystalline cellulose; hydroxypropyl cellulose; polyethylene glycol 6000; hydrogenated vegetable oil and silica colloidal anhydrous.
- Film coating: polyvinyl alcohol; talc; macrogol 3350; titanium dioxide and iron oxide red (E172).

#### **What Plavivor looks like and contents of the pack**

Pink, oval film-coated tablet.

Pack size: 10 (ten) tablets are placed in Alu/Alu blister. 3 (three) blisters with a leaflet in carton box.

#### **Marketing Authorisation Holder and Manufacturer**

Adipharm EAD  
130, Simeonovsko shosse Blvd., 1700 Sofia  
Bulgaria

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