

Clopidogrel Bisulfate

DESCRIPTION:

Antiplex® contains clopidogrel, an antiplatelet medicinal product.

Inactive Ingredients: Microcrystalline cellulose, mannitol, pregelatinised starch, croscarmellose sodium, sodium stearyl fumarate, talc, red ferric oxide (E172), hypromellose, titanium dioxide, macrogol.

PHARMACOLOGY:

Clopidogrel, the active ingredient in **Antiplex®** tablets, belongs to a group of medicines called antiplatelet medicinal products.

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

Antiplex® 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).

INDICATIONS:

Antiplex® is prescribed to help prevent blood clots and reduce the risk of these severe events because:

- The patient has a condition of hardening of arteries (also known as atherothrombosis), and
- The patient has previously experienced a heart attack, stroke or has a condition known as peripheral arterial disease, or
- The patient has experienced a severe type of chest pain known as "unstable angina" or "myocardial infarction" (heart attack). In this case the patient should also be given acetylsalicylic acid by his doctor.

CONTRAINDICATIONS:

The patient should not take **Antiplex®**:

- If he is hypersensitive (allergic) to clopidogrel or any of the other ingredients of **Antiplex®**;
- If he has a medical condition that is currently causing bleeding such as a stomach ulcer;
- If he suffers from severe liver disease;
- If she is breast-feeding.

If the patient thinks he may have any of these problems, or if he is in any doubt at all, he should consult his doctor before taking **Antiplex®**.

SIDE EFFECTS:

Like all medicines, **Antiplex®** can have side effects.

The most common side-effect reported with **Antiplex®** is bleeding such as bruising, haematoma, nose bleed, blood in the urine, bleeding in the stomach or bowels. In a small number of cases, bleeding in the eye, inside the head, the lung or the joints has also been reported.

The other side effects reported with **Antiplex®** are:

- Diarrhea, abdominal pain, constipation, nausea, vomiting, indigestion or heartburn;
- Vertigo, headache, decrease in blood pressure, confusion, hallucinations;
- Skin disorders such as rashes and itching, generalized allergic reactions;
- Joint pain, fever, taste disorders.

The patient should immediately contact his doctor if he experiences:

- Fever, signs of infection or extreme tiredness due to rare decrease of some blood cells.
- Jaundice as cases of liver disorders have been very rarely reported.

If the patient experiences prolonged bleeding when taking Antiplex®

If the patient cuts or injures himself, it may take slightly longer than usual for bleeding to stop. This is linked to the way his medicine works. For minor cuts and injuries e.g., cutting himself, shaving, this is of no concern. However, if the patient is in any doubt at all, he should contact his doctor straightaway. If he notices any side effects not mentioned in this leaflet, he should inform his doctor or pharmacist.

WARNINGS AND PRECAUTIONS:

The effect of clopidogrel is reduced in patients who are poor metabolizers of this active substance, since they do not effectively convert clopidogrel to its active form in the body. The use of other antiplatelet medications or alternative dosing strategies for clopidogrel in these patients is advised.

Tests are available to identify genetic differences in CYP2C19, the enzyme primarily responsible for the formation of the active metabolite of **Antiplex®**.

If any of the situations mentioned below apply to the patient, he should tell his doctor before taking **Antiplex®**:

- if he has a risk of hemorrhage such as:
 - a medical condition that puts him at risk of internal bleeding (such as stomach ulcer).
 - a blood disorder that makes him prone to internal bleeding (bleeding inside any tissues, organs or joints of his body).
 - a recent serious injury.
 - a recent surgery (including dental).

- a planned surgery (including dental) in the next seven days.

- if he is taking another type of medication.
- If he has kidney or liver disease.

Concomitant use of clopidogrel and omeprazole or esomeprazole should be discouraged, two studies conducted recently confirmed that omeprazole can reduce the levels of the active form of clopidogrel in the blood and reduce its antiplatelet effects.

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

Pregnancy: If the patient is pregnant or suspects that she is pregnant, she should tell her doctor or pharmacist before taking **Antiplex®**. If she becomes pregnant while taking **Antiplex®**, she should consult her doctor immediately.

Breast-feeding: If the patient is a mother breast-feeding a baby, she should not take **Antiplex®**.

Driving and using machines: **Antiplex®** is unlikely to affect the ability to drive or to use machines.

This product contains:

Mannitol: May have a mild laxative effect.

DRUG INTERACTIONS:

Some other medicines may influence the use of **Antiplex®** or vice versa. The patient should inform his doctor or pharmacist if he is taking or has recently taken any other medicines, even those not prescribed.

The use of warfarin with **Antiplex®** is not recommended.

The patient should specifically tell his doctor if he takes a non-steroidal anti-inflammatory medicinal product, or if he takes heparin.

If the patient has experienced severe chest pain (unstable angina or heart attack), he may be prescribed **Antiplex®** in combination with acetylsalicylic acid. An occasional use of acetylsalicylic acid (no more than 1000 mg in any 24 hour period) should generally not cause a problem, but prolonged use in other circumstances should be discussed with the doctor.

DOSAGE AND ADMINISTRATION:

Antiplex® should always be taken exactly as the doctor has instructed the patient. He should check with his doctor or pharmacist if he is unsure.

The usual dose is one 75 mg tablet of **Antiplex®** per day to be taken orally with or without food. He should take his medicine regularly and at the same time each day.

In addition, if the patient has experienced severe chest pain, his doctor may give him 300 mg of **Antiplex®** (4 tablets of 75 mg) at the start of treatment.

Duration of treatment: The patient should take **Antiplex®** for as long as his doctor continues to prescribe it.

If the patient takes more Antiplex® than he should: He should contact his doctor or the nearest emergency department because of increased risk of bleeding.

If the patient forgets to take Antiplex®: If he forgets to take a dose of **Antiplex®**, but remembers within 12 hours of his usual time, he should take his tablet straightaway and then take his next tablet at the usual time.

If he forgets for more than 12 hours, he should simply take the next single dose at the usual time. He should not take a double dose to make up for the forgotten individual doses.

Effects when treatment with Antiplex® is stopped: The patient should not stop the treatment. He should contact his doctor or pharmacist before stopping.

PRESENTATIONS:

Antiplex® 75 Tablets: Packs of 30 film coated tablets. Each tablet contains 75 mg Clopidogrel (as clopidogrel bisulfate).

STORAGE CONDITIONS:

Store below 30°C.

This is a medicament.

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold you the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and its risks.
- Do not, by yourself, interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.