

CLOPLAV® HIKMA PHARMACEUTICALS

Clopidogrel (As Bisulphate)

ACTION

Clopidogrel, the active ingredient in Cloplav 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).

Cloplav 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

You have been prescribed Cloplav to help prevent blood clots and reduce the risk of these severe events because:

- You have a condition of hardening of arteries (also known as atherothrombosis), 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.

DOSAGE AND ADMINISTRATION

The usual dose is one 75mg tablet of Cloplav per day to be taken orally with or without food. You should take your medicine regularly and at the same time each day. In addition, if you have experienced severe chest pain, your doctor may give you 300mg of Cloplav (4 tablets of 75mg) at the beginning of treatment.

If you forget to take Cloplav:

If you forget to take a dose of Cloplav, 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 doses.

CONTRAINDICATIONS

Do not take Cloplav:

- If you are hypersensitive (allergic) to clopidogrel or any of the other ingredients of Cloplav.
- If you have a medical condition that is currently causing bleeding such as a stomach ulcer.
- If you suffer from severe liver disease.
- If you are breast-feeding.

WARNINGS AND PRECAUTIONS

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

- If you have a risk of haemorrhage 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).
 - A recent, serious injury.
 - A recent surgery (including dental).
 - A planned surgery (including dental) in the next seven days.
 - If you are taking another type of medication.
 - If you have kidney or liver disease.
 - Concomitant use of omeprazole or esomeprazole.
- Cloplav is not intended for use in children or adolescents less than 18 years of age.

Pregnancy

If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist

before taking Cloplav. If you become pregnant while taking Cloplav, consult your doctor immediately.

Breast-feeding

If you are a mother breast-feeding a baby, you should not take Cloplav.

Driving and using machines

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

Drug Interactions

Some other medicines may influence the use of Cloplav or vice versa. Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

The use of warfarin (a drug used to reduce blood clotting) with Cloplav is not recommended.

You should specifically tell your doctor if you take a non-steroidal anti-inflammatory medicinal product, usually used to treat painful and/or inflammatory conditions of muscle or joints, or if you take heparin, another drug used to reduce blood clotting.

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed Cloplav 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 1000 mg in any 24 hour period) should generally not cause a problem, but prolonged use in other circumstances should be discussed with your doctor.

SIDE EFFECTS

The most common side-effect reported with Cloplav 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 Cloplav are:

- Diarrhoea, abdominal pain, constipation, nausea, vomiting, indigestion or heart burn.
- Vertigo, headache, decrease in blood pressure, confusion, hallucinations.
- Skin disorders such as rashes and itching, generalised allergic reactions.

- Joint pain, fever, taste disorders.

Immediately contact your doctor if you experience:

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

If you experience prolonged bleeding when taking Cloplav:

If you cut or injure yourself, it may take slightly longer than usual for bleeding to stop. This is linked to the way your medicine works. For minor cuts and injuries e.g. cutting yourself, shaving, this is of no concern. However, if you are in any doubt at all, you should contact your doctor straightaway.

OVERDOSAGE

If you take more Cloplav than you should, contact your doctor or the nearest emergency department because of the increased risk of bleeding.

STORAGE

Store below 25°C.

PRESENTATIONS

Tablets:

Cloplav 75: Clopidogrel (As Bisulphate) 75 mg

Excipients: Mannitol, Microcrystalline Cellulose, Hydroxy Propyl Cellulose, Polyethylene Glycol, Hydrogenated Vegetable Oil, Instacoat Universal IC-U-3164 (Brown).