

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

CLOPIWIN® 75 mg Film-coated tablets

CLOPIWIN® 300 mg Film-coated tablets

Clopidogrel

CLOPIWIN 75 mg contains sugar (3 mg lactose and 68,9 mg mannitol).

CLOPIWIN 300 mg contains sugar (12 mg lactose and 275,7 mg mannitol).

Read all of this leaflet carefully before you start taking CLOPIWIN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- CLOPIWIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What CLOPIWIN is and what it is used for

CLOPIWIN contains the active substance clopidogrel which belongs to a group of medicines called

antiplatelet medicines. Platelets are very small structures in the blood which clump together during blood clotting. By preventing this clumping, antiplatelet medicines reduce the chances of blood clots forming (a process called thrombosis).

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

- you have a condition of hardening of arteries (also known as atherosclerosis), 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.

2. What you need to know before you take CLOPIWIN

Do not take CLOPIWIN:

- if you are hypersensitive (allergic) to the active ingredient clopidogrel or to any of the other ingredients of CLOPIWIN (listed in section 6).
- if you have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding within the brain.
- if you suffer from severe liver disease.
- if you are pregnant or breastfeeding.
- if you suffer from a dysfunction of, or reduction in, blood platelets which increases risk of bleeding and bruising.
- if you suffer from an inherited blood disorder or develop a blood disorder (haemophilia A) that causing insufficient blood clotting.

If you think any of these apply to you, or if you are in any doubt at all, consult your doctor before taking CLOPIWIN.

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

Warnings and precautions

Special care should be taken with CLOPIWIN, tell your doctor or health care provider before taking

CLOPIWIN:

- 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 tissue, 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.
 - a planned spinal, epidural anaesthetic or a lumbar puncture in the next seven days.
- if you have had a clot in an artery of your brain (ischaemic stroke) which occurred in the last seven days.
- if you have kidney or liver disease.
- if you are taking any other type of medication (see Other medicines with CLOPIWIN).

Take special care while you are taking CLOPIWIN:

You should 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).

- You should tell your doctor and anaesthetist that you take CLOPIWIN:
 - if surgery (including dental) is planned.

- if you have any stomach or abdominal pain or bleeding in the stomach or bowels (red stools or black stools).
- 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 4).
- Your doctor may order blood tests.

Children and adolescents

CLOPIWIN is not intended for use in children or adolescents less than 18 years of age (see Do not take CLOPIWIN).

Other medicines with CLOPIWIN

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

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

You should specifically tell your doctor if you take

- Medicines that may increase your risk of bleeding such as:
 - oral anticoagulants, medicines used to reduce blood clotting, (such as warfarin).
 - aspirin or non-steroidal anti-inflammatory medicines usually used to treat painful and/or inflammatory conditions of muscle or joints.
 - heparin or any other injectable medicine used to reduce blood clotting.
 - other antiplatelet medicines used to reduce blood clotting.
 - selective serotonin reuptake inhibitors (SSRIs) (including but not restricted to fluoxetine or fluvoxamine), medicines usually used to treat depression.
 - rifampicin (used to treat severe infections such as tuberculosis (TB)).

- 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 infections)
- carbamazepine, a medicine to treat some forms of epilepsy
- moclobemide, medicine to treat depression
- repaglinide, medicine to treat diabetes
- paclitaxel, medicine to treat cancer
- rosuvastatin (used to lower your cholesterol level)
- opioids: while you are treated with CLOPIWIN, you should inform your doctor before being prescribed any opioid (used to treat severe pain, e.g. morphine).

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed CLOPIWIN in combination with acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever. Contact your doctor before using other aspirin containing medicines concomitantly with CLOPIWIN.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking CLOPIWIN.

CLOPIWIN should not be used during pregnancy or breastfeeding (See: Do not take CLOPIWIN).

Driving and using machines

CLOPIWIN should not affect your ability to drive or to use machines.

CLOPIWIN contains lactose and castor oil

If you have been told by your doctor that you have intolerance to some sugars (e.g. lactose), contact your doctor before taking CLOPIWIN.

CLOPIWIN also contains hydrogenated castor oil which may cause stomach upset and diarrhoea.

3. How to take CLOPIWIN

Do not share medicines prescribed for you with any other person.

Always take CLOPIWIN exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

The usual dose is one 75 mg tablet of CLOPIWIN 75 mg per day to be taken orally with a glass of water, with or without food.

If you have experienced severe chest pain (unstable angina or heart attack), your doctor may give you 300 mg of clopidogrel (1 tablet of CLOPIWIN 300 mg or 4 tablets of CLOPIWIN 75 mg) once at the start of treatment. Thereafter, the recommended dose is one CLOPIWIN 75 mg tablet per day as described above.

You should take your medicine regularly and at the same time each day.

You should take CLOPIWIN for as long as your doctor continues to prescribe it.

If you take more CLOPIWIN than you should

In the event of overdosage, immediately consult your doctor or pharmacist because of the increased risk of bleeding. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CLOPIWIN

If you forget to take a dose of CLOPIWIN, 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 dose.

If you stop taking CLOPIWIN

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

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

4. Possible side effects

CLOPIWIN can have side effects.

Not all side effects reported for CLOPIWIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLOPIWIN, please consult your health care provider for advice.

If any of the following happens, stop taking CLOPIWIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling in the mouth, tongue, face or throat, fainting or severe skin disorders such as rashes, itching, blisters or peeling of the skin. These may be the signs of an allergic reaction
- widespread serious skin rash, hives or bumps under the skin, including symptoms such as extensive skin damage, blisters or skin peeling, ulcers of mouth, throat, nose, genitals and eyes, fever, enlarged lymph nodes and other body organs involvement
- hypersensitivity reactions with chest or abdominal pain

These are all very serious side effects. If you have them, you may have had a serious reaction to CLOPIWIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fever, signs of infection or extreme tiredness. These may be due to a decrease of some blood cells.
- if you develop a medical condition known as thrombotic thrombocytopenic purpura (also known as TTP) – the symptoms may include fever, 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 Warnings and precautions in section 2.

- 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 (also see section 2).
- inflammation of the pancreas, may cause severe abdominal pain with or without back pain.

These are all serious side effects. you may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Bleeding:
 - The most frequent side effect which has been seen with CLOPIWIN is bleeding.** Bleeding may occur as bleeding in the stomach or bowels, bruising, haematoma (unusual bleeding or bruising under the skin), nosebleed, 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 CLOPIWIN:**
If you cut or injure yourself, it may take slightly longer than usual for bleeding to stop. This is linked to the way CLOPIWIN 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 Warnings and precautions in section 2).
- diarrhoea
- abdominal pain
- indigestion or heartburn.

Less frequent side effects:

- headache

- stomach ulcer
- vomiting
- nausea
- constipation
- excessive gas in stomach or intestines
- rashes, itching
- dizziness
- sensation of tingling and numbness; vertigo

Frequency unknown:

- enlarged breasts in males
- fever
- breathing difficulties sometimes associated with cough or infection of the lungs
- skin allergy, rash, hives or itching
- inflammation of the mouth (stomatitis)
- decrease in blood pressure; confusion
- hallucinations
- joint pain
- muscular pain
- changes in the way things taste or loss of taste of food
- inflammation of small vessels
- persistent low blood sugar symptoms
- bleeding disorder causing insufficient blood clotting (acquired haemophilia A)
- changes in your blood or urine tests

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, contact your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can report any side effects directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**” found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.
By reporting side effects, you can help provide more information on the safety of CLOPIWIN.

5. How to store CLOPIWIN

CLOPIWIN 75 mg: Store at or below 25 °C.

CLOPIWIN 300 mg: Store at or below 30 °C.

Protect from light.

Do not remove PVC/PVDC blisters from the carton until required.

Do not use CLOPIWIN after the expiry date stated on the carton and on the blister.

Store all medicine out of reach of children.

Do not use CLOPIWIN if you notice any visible sign of deterioration.

Return all unused tablets to your pharmacist for safe disposal.

6. Contents of the pack and other information

What CLOPIWIN contains

The active substance is clopidogrel (as hydrogen sulphate).

The other inactive ingredients are mannitol (sugar), hydrogenated castor oil, microcrystalline cellulose, macrogol 6000 and low-substituted hydroxypropyl cellulose in the tablet core, and lactose monohydrate (milk sugar), hypromellose, triacetin, red iron oxide (E172), titanium dioxide (E171) and carnauba wax in the tablet coating.

What CLOPIWIN looks like and contents of the pack

CLOPIWIN 75 mg tablets are pink, round, slightly biconvex, film-coated tablets engraved with «75» on one side and «1171» on the other side.

CLOPIWIN 75 mg is available in packs of 28 or 30 tablets packed in PVC/PVDC or all aluminium blister strips in cardboard cartons.

CLOPIWIN 300 mg tablets are pink, oblong, film-coated tablets engraved with «300» on one side and «1332» on the other side.

CLOPIWIN 300 mg is available in packs of 4, 30 or 100 tablets and are supplied in aluminium blister strips. The packs consist of either 4 tablets per blister strip and one blister strip is packed into a cardboard carton, or

10 tablets per blister strip and 3 or 10 blister strips are packed into a cardboard carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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sanofi-aventis south africa (pty) ltd

Clopiwin 75 mg / 300 mg film-coated tablets
Clopidogrel hydrogen sulphate equivalent to 75 mg or 300 mg clopidogrel

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Registration numbers

CLOPIWIN 75 mg: 41/8.2/0051

CLOPIWIN 300 mg: 44/8.2/0042