



Clopi TAD® 75 mg film-coated tablets

Clopidogrel

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

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Clopi TAD is and what it is used for
2. Before you take Clopi TAD
3. How to take Clopi TAD
4. Possible side effects
5. How to store Clopi TAD
6. Further information

1. WHAT CLOPI TAD IS AND WHAT IT IS USED FOR

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

Clopi TAD 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).

You have been prescribed Clopi TAD 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 atherosclerosis), and
- You have previously experienced a heart attack, stroke or have a condition known as peripheral arterial disease.

2. BEFORE YOU TAKE CLOPI TAD

Do not take Clopi TAD

- If you are allergic (hypersensitive) to clopidogrel or any of the other ingredients of Clopi TAD;
- 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 think any of these apply to you, or if you are in any doubt at all, consult your doctor before taking Clopi TAD.

Take special care with Clopi TAD

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

- 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).
 - a recent serious injury
 - a recent surgery (including dental)
 - a planned surgery (including dental) in the next seven days
 - if you have had a clot in an artery of your brain (ischaemic stroke) which occurred within the last seven days
 - if you have kidney or liver disease.

While you are taking Clopi TAD:

- 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 that includes fever and bruising under the skin that may appear as red pinpoint dots (also known as Thrombotic Thrombocytopenic Purpura or TTP), 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 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 'Possible side effects').
- Your doctor may order blood tests.

Clopi TAD is not intended for use in children or adolescents.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

You should specifically tell your doctor if you take

- oral anticoagulants, medicines used to reduce blood clotting,
- a non-steroidal anti-inflammatory medicine, usually used to treat painful and/or inflammatory conditions of muscle or joints,
- heparin or any other medicine used to reduce blood clotting,
- a proton pump inhibitor (e.g. omeprazole) for upset stomach,
- fluconazole, voriconazole, ciprofloxacin, or chloramphenicol, medicines to treat bacterial and fungal infections,
- cimetidine, medicine to treat upset stomach,
- fluoxetine, fluvoxamine, or moclobemide, medicines to treat depression,
- carbamazepine, or oxcarbazepine, medicines to treat some forms of epilepsy,
- ticlopidine, other antiplatelet agent.

An occasional use of acetylsalicylic acid (no more than 1000 mg in any 24 hour period), a substance present in many medicines used to relieve pain and lower fever, should generally not cause a problem, but prolonged use in other circumstances should be discussed with your doctor.

Taking Clopi TAD with food and drink

Clopi TAD may be taken with or without food.

Pregnancy and breast-feeding

It is preferable not to use this product during pregnancy and breast-feeding.

If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking Clopi TAD. If you become pregnant while taking Clopi TAD, consult your doctor immediately as it is recommended not to take clopidogrel while you are pregnant.

While taking Clopi TAD, consult your doctor about the breast feeding of a baby.

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

Driving and using machines

Clopi TAD is unlikely to affect your ability to drive or to use machines.

Important information about some of the ingredients of Clopi TAD

Clopi TAD contains hydrogenated castor oil which may cause stomach upset and diarrhoea.

3. HOW TO TAKE CLOPI TAD

Always take Clopi TAD exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one 75 mg tablet of Clopi TAD per day to be taken orally with or without food, and at the same time each day.

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

If you take more Clopi TAD than you should:

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

If you forget to take Clopi TAD:

If you forget to take a dose of Clopi TAD, 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 a forgotten tablet dose.

If you stop taking Clopi TAD:

Do not stop the treatment. Contact your doctor or pharmacist before stopping.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Clopi TAD 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 rare decrease of some blood cells.
- signs of liver problems 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 'Take special care with Clopi TAD').
- swelling in the mouth or skin disorders such as rashes and itching, blisters of the skin. These may be the signs of an allergic reaction.

The most common side effect (affects 1 to 10 patients in 100) is bleeding.

Bleeding may occur as bleeding in the stomach or bowels, bruising, haematoma (unusual bleeding or bruising under the skin), nose bleed, 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 Clopi TAD

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 as it prevents the ability of blood clots to form. For minor cuts and injuries e.g., cutting yourself, shaving, this is of no concern. However, if you are concerned by your bleeding, you should contact your doctor straightaway (see section 2 'Take special care with Clopi TAD').

Other side effects reported are

Common side effects (affects 1 to 10 patients in 100): Diarrhoea, abdominal pain, indigestion or heartburn.

Uncommon side effects (affects 1 to 10 patients in 1,000): Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, rashes, itching, dizziness, sensation of tingling and numbness.

Rare side effect (affects 1 to 10 patients in 10,000): Vertigo.

Very rare side effects (affects less than 1 patient in 10,000): jaundice; severe abdominal pain with or without back pain; fever, breathing difficulties sometimes associated with cough; generalised allergic reactions; swelling in the mouth; blisters of the skin; skin allergy; inflammation of the mouth (stomatitis); decrease in blood pressure; confusion; hallucinations; joint pain; muscular pain; changes in the way things taste.

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

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

5. HOW TO STORE CLOPI TAD

Keep out of the reach and sight of children.

Do not use Clopi TAD after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture and light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Clopi TAD contains

- The active substance is clopidogrel. Each film-coated tablet contains 75 mg of clopidogrel (as hydrochloride).
- The other ingredients are microcrystalline cellulose, colloidal anhydrous silica, crospovidone (type A), macrogol 6000, hydrogenated castor oil in the tablet core and hydroxypropylcellulose (E463), titanium dioxide (E171), red iron oxide (E172), talc and propylene glycol in the film-coating.

What Clopi TAD looks like and contents of the pack

The film-coated tablets are pink, round and slightly convex. Boxes of 28 film-coated tablets in blisters are available.

Marketing Authorisation Holder

TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

Manufacturer

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