PACKAGE LEAFLET: INFORMATION FOR THE USER

CLOPRA® 75 mg Film Tablet

For orally administration.

Active substance: 97.875 mg clopidogrel bisulfate equivalent to 75 mg clopidogrel.

Excipients: Beta lactose anhydrous (obtained fromcows milk), microcrystalline cellulose PH 102, pregelatinised starch, colloidal silicon dioxide, hydroxypropyl cellulose (L-HPC), hydrogenetad castor oil, O P A D R Y I I 3 1 K 3 4 1 2 7 p i n k (Lactose monohydrate((obtained fromcows milk),, hypromellose, titanium dioxide, triacetin, red iron oxide, yellow iron oxide, black iron oxide, deionized water

Please read this leaflet carefully before you start using 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT CLOPRA® IS AND WHAT IT IS USED FOR

- CLOPRA® consists of 75 mg clopidogrel in each tablet. Pink, 28 film tablets in blister packaging.
- CLOPRA® contain clopidogrel which 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).
- CLOPRA® 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 CLOPRA® to help prevent blood clots and reduce the risk of these sever 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). 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.
  - You have 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 have been told that 'oral anticoagulants' are more effective than acetylsalicylic acid or the combined use of CLOPRA® and acetyl salicylic acid for this condition. Your doctor should have prescribed CLOPRA® plus acetylsalicylic acid if you cannot take 'oral anticoagulants' and you do not have a risk of major bleeding.

2. BEFORE YOU USE CLOPRA®

Do not use CLOPRA®

- If you are allergic (hypersensitive) to clopidogrel or any of the other ingredients of CLOPRA®.
- 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
- If you are taking repaglinide

Take special care with CLOPRA®

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

- 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 injury.
- A recent surgery (including dental).
- A planned surgery (including dental) in the next seven days.

If you use any other medicinal products (See *Other medicines and* CLOPRA®)

- If you are taking any medicines belonging to the proton pump inhibitor drug group for the treatment of stomach disorders (see section "Use of other drugs with CLOPRA®)
- If you have kidney and liver disease.
- If you have prolonged clotting time, you may be diagnosed haemophilia which known as defect on clotting. Diagnoses and treatment of this disease should be controlled by special doctor. In this case, you should stop to take CLOPRA®.
- In patients with high risk of stroke due to circulatory failure resulting in clot formation that has similar disorder or stroke recently, concomitant use of aspirin and clopidogrel has been shown to increase large bleeds. Therefore, except when proven to be beneficial, you should be cautious in using these two drugs together.
- If a clot has occurred in a vein in your brain within the last 7 days (ischemic stroke)
- If you have had an allergic reaction from another group (eg clopidogrel or prasugrel) from the same group, you may also develop an allergic reaction to CLOPRA (rash, swelling of the throat on the lips, reduction of blood platelets or white blood cells).

While you are taking Clopra, inform your doctor in any of the following situations:

- 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 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)
- If you cut or injure yourself, it may take longer than usual for bleeding to stop.

If any of these warnings applies to you even for any period in the past please consult your doctor.

CLOPRA® is not intended for use in children or adolescents.

Using with food and drink:

Nutrition does not affect the absorption of CLOPRA®. CLOPRA® may be taken with or without food.

Pregnancy

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

CLOPRA® is not recommended for use during pregnancy.

Tell your doctor if you notice that you are pregnant while you are using this medicine.

Lactation

Ask your doctor or pharmacist for advice before taking this medicine

It is not recommended to breastfeed your baby when using CLOPRA®.

If you are breast-feeding or planning to breast-feed, talk to your doctor before taking CLOPRA®.

Driving and using machines

CLOPRA® unlikely to affect your ability to drive or to use machines.

Important information on some inactive ingredients of CLOPRA®

CLOPRA® contains lactose. If you have been told by your doctor that you have intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.

CLOPRA® contains hydrogenated castor oil which may cause stomach upset or diarrhoea.

Other medicines and CLOPRA®

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines especially mentioned drugs in below:

- Oral anticoagulants such as Warfarin (medicines used to reduce blood clotting). These drugs are not recommended for co-administration with CLOPRA®.
- Non-steroidal anti-inflammatory medicines (usually used to treat painful and/or inflammatory conditions of muscle or joints)
- Heparin or any other medicine used to reduce blood clotting
- Medicines that are belongs to proton pump inhibitors class such as omeprazole, esomeprazole and cimetidine (used to treat upset stomach)
- Voriconazole, fluconazole, ciprofloxacine or chloramphenicol (used to treat bacterial and fungal enfections)
- Fluvoxamine, fluoxetine or moclobemid (used to treat depression)

- Carbamazepine, oxcarbazepine (used to treat some forms of epilepsy)
- Ticlopidine, (other antiplatelet agents)

The use of these drugs with CLOPRA® is not recommended.

- Efavirenz (a drug used in the treatment of AIDS)
- Repaglinide (a drug used in the treatment of diabetes)
- Paclitaxel (a drug used to treat cancer)

If you are using one of these medicines, you should definitely tell your doctor.

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed CLOPRA® 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 1,000 mg in any 24 hour period) should generally not cause a problem, but prolonged use in other circumstances should be discussed with your doctor.

If you need to use any other drugs when you take CLOPRA®, you should inform your doctor.

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

3. How to use CLOPRA®?

Your doctor will tell you how you should use your medicine.

Always use CLOPRA® exactly as your doctor has told you. You should 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 Plavix per day to be taken orally with or without food, and at the same time each day.

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

Take your medicine at the same time each day. Taking your tablets every day at the same time will help you get the best effect on your disease. This may also remind you to take your medicine.

Tell your doctor that you take CLOPRA®, if any surgery (including dental) is planned to you.

Take your medicine as information in this leaflet, if your doctor not gives you any other advice.

Method of administration:

Take one tablet with adequate amount of water (a glass of water), without chewing, with or without food.

Using in other ages:

In children: CLOPRA® is not suitable for use in children or adolescents.

In elderly: No special dosing needed. Patients over 75 years of age who have had a certain type of heart attack (acute myocardial infarction with ST elevation) should be started clopidogrel therapy without loading dose.

Special use cases:

Allergic cross reactivity: Patients who have hypersensitivity to antiplatelet agents should use with special care.

Renal failure: Patients who have renal failure should use with special care.

Hepatic failure: CLOPRA® is not recommended patients who have severe hepatic failure. Patients who have mild and moderate hepatic failure should use with special care.

If you have an impression that the effect of CLOPRA® is too strong or weak, talk to your doctor or pharmacist.

If you use more CLOPRA® than you should

Tell your doctor or your pharmacist, if you accidentally use more than you were told.

Over dosage may increase risk of bleeding.

If you accidentally take only one more tablet, side effect may not be occurred. If you accidentally take more than one tablet, you should contact your doctor or the nearest hospital emergency department. Take the tablets or the package of your medicine along with you to show your doctor.

If you forget to use CLOPRA®

If you forget to take a dose of CLOPRA®, 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 dose.

Effects that may occur when treatment with CLOPRA® is terminated

If you stop using CLOPRA® without your doctor's recommendation, risk of clotting in the blood vessels may increase, then it may lead to atherothrombotic events (such as stroke, heart attack, or death).

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

4. Possible side effects

Like all medicines, CLOPRA® can cause side effects, although not everybody gets them.

Side effects are classified as below:

Very common: It can be seen in at least 1 out of 10 patients.

Common: Less than 1 in 10 people, more than 1 in 100 people.

Not common: Less than 1 in 100 people, more than 1 in 1000 people.

Rare: Less than 1 in 1.000 people, more than 1 in 10.000 people.

Very rare: Less than 1 in 10.000 people.

Unknown: Cannot be estimated from the available data

You should stop taking CLOPRA® and get IMMEDIATELY medical help if you experience symptoms such as:

- 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 and/or confusion
- 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

Common side effects

- Swelling in the tissue
- Nose bleeding
- Bleeding in the stomach or bowels,
- diarrhoea,

- upper abdominal pain,
- Indigestion or heartburn
- Bruising
- Bleeding around surgical tissue

Not common side effects:

- Decreased blood platelet (thrombocytopenia) and white blood cells/leukocytes (leucopenia, eosinophilia)
- Bleeding inside the head (In a small number of cases death has been reported),
- headache,
- dizziness,
- sensation of tingling / chills (paresthesia)
- Bleeding in the eye
- Stomach ulcer,
- duedonal ulcer,
- inflammation in the stomach mucosa,
- vomiting,
- nausea,
- constipation,
- dyspepsy
- Rashes,
- itching,
- bleeding on skin (purpura)
- Blood in the urine
- Prolonged bleeding time,
- decreased white blood cells (neutrophils),
- decreased blood platelet

Rare side effects

- Serious decreased white blood cells (neutropenia, including serious neutropenia)
- Temporary drowsiness accompanied by loss of balance and blurring of eyes (Vertigo)
- Bleeding in the outer or posterior part of the abdominal wall (retroperitoneal bleeding)
- Gynecomastia (breast enlargement in men)

Very rare side effects

- Fever,
- bleeding which appears under the skin as red pinpoint dots,
- confusion,
- headache and decreased thrombocytes which known as thrombotic thrombocytopenic purpura (TTP),
- anaemia due to the defect in bone marrow which leads to produce blood cells (aplastic anaemia),
- deficiency of blood cells structure (pancytopenia),
- decreased white blood cells called granulocytes which leads to wounds on mouth, throat and skin (agranulocytosis),
- serious decreased thrombocyte (thrombocytopenia),
- decrased granuler leucocytes (granulaocytopenia),
- aneamie
- urticaria,
- oedema,
- joint pain,
- swelling on lymph node, signs of hypersensitivty (serum sickness),
- Allergic (anaflactic) reactions
- to seem to see, hear, feel, or smell something that does not exist **(**hallucinations), confusion
- Changes in taste of food
- Serious bleeding,
- bleeding in surgical tissue,
- vasculitis,
- Low blood pressure (hypotension)
- Hemorrhage in the respiratory tract (hemoptysis) (blood in saliva, bleeding in the lungs)
- Bronchial vasoconstriction,
- pneumonia (breathing difficulties sometimes associated with cough),
- eosinophilic pneumonia
- Bleeding in the stomach or bowels, bleeding in peritonum, pancreatitis, colitis, stomatitis
- Pancreatitis
- Colon inflammation

- Mouth inflammation
- Acute liver failure,
- jaundice,
- defect on liver function tests
- Blisters on skin (erythema multiforme, Steve-Johnson Syndrom, toxic epidermal necrolysis, etc),
- rashes with blisters, , urticaria, hypersensitivity,
- increased leucocytes and DRESS syndrome with systemic effects,
- swelling on face and throat signs of allergy (angioedema)
- dermatitis with rash (egzema),
- redness especially on arm and leg skin (lichen planus)
- Bleeding in musculoskeletal system (hemarthrosis),
- arthritis,
- joint pain,
- muscle pain
- Inflammation of renal capillaries associated with renal diseases which known as glomerulonephritis,
- Increased blood creatinine

Unknown side effects

- Hemophilia A which is blood clotting disorder
- Allergic reactions associated with co-administration of other medicines which effect on blood platelet with CLOPRA®

If you experience prolonged bleeding when taking CLOPRA®

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. 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.

If you get any side effects not listed in this leaflet, talk to your doctor, 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.

5. How to store MOMETIX

Keep CLOPRA® out of the sight and reach of children and its own package.

Store below 25°C.

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

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

Do not throw away any expired or unused medicines.

Marketing Authorisation Holder and Manufacturer

Drogsan İlaçları San. ve Tic. A.Ş.

Oğuzlar Mah. 1370. Sok. 7/3

06520 Balgat – Ankara / TURKEY

Site of Manufacturing

Drogsan İlaçları San. ve Tic. A.Ş.

06760 Çubuk – Ankara / TURKEY

This leaflet was last approved in 30.07.2018.