

ONECLAPZ 75 (Clopidogrel Tablets 75mg)

Clopidogrel Bisulphate equivalent to Clopidogrel 75mg

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What is ONECLAPZ 75 used for

ONECLAPZ 75 is indicated for the prevention of blood clot formation inside blood vessels, such as:

- You suffer from heart attack (from a few days until less than 35 days), stroke (from 7 days until less than 6 months) or condition known as artery narrowing disease
- You have experienced a severe type of chest pain known as unstable angina or heart attack. The treatment of this condition may require your doctor to place a stent in the blocked or narrowed artery to restore effective blood flow
- You have irregular heart rhythm called fibrillation where your doctor may combine with another drug called acetyl salicylic acid to prevent stroke

How ONECLAPZ 75 works

ONECLAPZ 75 belongs to a group of medicines called anti-platelets.

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

Before you use ONECLAPZ 75

-When you must not use it

Do not take ONECLAPZ 75 if:

- You are allergic to Clopidogrel or any of the ingredients in this product
- You have a medical condition that is currently causing bleeding such as a stomach ulcer, bleeding within the brain or any other bleeding disorders
- You suffer from severe liver disease

If you think any of the above applies to you or you are in doubt, please consult your doctor before consuming this medication.

-Before you start to use it

Special care should be taken before you start taking ONECLAPZ 75. If any of the below apply to you, please inform your doctor first:

- If you have a risk of bleeding. Appropriate tests should be done by your doctor to determine your risk of bleeding while on this medication.
- A blood disorder that makes you prone to internal bleeding (bleeding inside any tissues, organs or joints of your body)
- A recent serious injury (trauma)
- A recent surgery
- A planned surgery (including dental surgery)
- If you have any known lesions in your intestines or eye
- If you have kidney or liver disease
- If you are taking any pain killers of the non-steroidal anti-inflammatory drugs group (NSAIDs) including COX-2 inhibitors, blood thinners such as heparin or glycoprotein IIb/IIIa inhibitors (a type of blood thinning agent).

- A recent stroke
- If you have known enzyme disorders which affects the proper metabolism of drugs

This product contains hydrogenated castor oil which may cause stomach upset and diarrhoea.

-Taking other medications

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 ONECLAPZ 75 or vice versa.

You should specifically tell your doctor if you take:

- Oral anticoagulants (medicines used to reduce blood clotting) such as warfarin or ticlopidine
- Pain killers such as non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. acetyl salicylic acid, naproxen) or COX-2 inhibitors (e.g. celecoxib)
- Thrombolytics, heparin or other injectable medicines used to reduce/ treat blood clots like glycoprotein IIb/IIIa inhibitors
- Medicines used to treat depression known as selective serotonin reuptake inhibitors (SSRIs)
- Medicines to reduce stomach acid in the proton pump inhibitor class

How to use ONECLAPZ 75

-How much to use

Always take ONECLAPZ 75 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure as the instructions in this leaflet may differ.

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If you have experienced severe chest pain, your doctor may give you 300mg of ONECLAPZ 75 (4 tablets of 75mg) once at the start of treatment. Then, the usual dose is 75mg (one tablet) per day.

Sometimes, your doctor may combine ONECLAPZ 75 with another medicine called acetylsalicylic acid depending on its necessity.

-When to use it

ONECLAPZ 75 is to be taken orally with or without food, and at the same time each day.

-How long to use it

Continue taking your medicine for as long as your doctor continues to prescribe it. Please talk to your doctor before you consider stopping treatment.

-If you forget to use it

If you forget to take a dose of ONECLAPZ 75 but remember within 12 hours of your usual time, take the tablet straightaway and then take your next tablet at your usual time.

If you forget for more than 12 hours, take the next dose at your usual time. Do not double the dose to make up for a missed dose.

-If you use too much (overdose)

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

While you are using it

-Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ONECLAPZ 75.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ONECLAPZ 75.

You should tell your doctor if a surgery (including dental surgery) is planned

You should also tell your doctor immediately if you develop a medical condition (also known as Thrombotic Thrombocytopenic Purpura (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. This is linked to the way this medication works as it prevents the ability of blood clots to form. If you are concerned about bleeding, contact your doctor right away.

Your doctor may order blood tests. ONECLAPZ 75 is not intended to be used in children and adolescents.

-Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking this medication or change the dosage without checking with your doctor.

-Things to be careful of

Driving and using machines:

- ONECLAPZ 75 is unlikely to affect your ability to drive or operate machinery

Pregnancy and Lactation:

- It is preferable not to take this medication during pregnancy. If you are pregnant or suspect that you are pregnant while on this medication, please inform your doctor or pharmacist immediately
- Do not breastfeed while on this medication. If you are planning to breastfeed, please consult your doctor or pharmacist prior to taking this medicine

Side effects

Like all medicines, ONECLAPZ 75 can cause side effects although not everyone will experience it.

Common side effects include bruising, nose bleeds, diarrhoea and abdominal pain

Uncommon side effects include blood in urine, headache, dizziness, rash and constipation.

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

You may report any side effects or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ONECLAPZ 75

-Storage

Store in a dry place below 30°C. Keep out of sight and reach of children.

-Disposal

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.

Product Description

-What it looks like

ONECLAPZ 75 is a pink coloured, round biconvex, bevelled edge, film coated tablet debossed with 'E' on one side and '34' on the other side.

-Ingredients

- Active ingredient(s)
Clopidogrel Bisulphate

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· Inactive ingredient(s)

Castor oil (hydrogenated),
macrogol 6000,
microcrystalline cellulose,
purified water, low
substituted hydroxypropyl
cellulose, opadry II pink,
crospovidone and mannitol.

-MAL number

MAL*****AZ

Manufacturer

Aurobindo Pharma Limited
Unit III, Survey No. 313 & 314,
Bachupally village, Bachupally
Mandal, Medchal- Malkajgiri
district, Telangana state, India

Product Registration Holder

Healol Pharmaceuticals Sdn Bhd
74-3, Jalan Wangsa Delima 6,
KLSC Wangsa Maju,
53300 Kuala Lumpur, Malaysia

Date of revision

-22/01/2024

Serial Number

NPRA(Rx/x)xxxxxx/xxxxx