PATIENT INFORMATION LEAFLET
CLOPIDOGREL ASPIRIN 75/75 mg PD

SCHEDULING STATUS

S3

CLOPIDOGREL ASPIRIN 75/75 mg PD film coated tablets

Clopidogrel and Acetylsalicylic acid (ASA) (aspirin)

CLOPIDOGREL ASPIRIN 75/75 mg PD contains sugar - lactose monohydrate 2,80 mg and mannitol 64 mg (sugar alcohol)

Read all of this leaflet carefully before you start taking CLOPIDOGREL ASPIRIN 75/75 mg PD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- CLOPIDOGREL ASPIRIN 75/75 mg PD 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 CLOPIDOGREL ASPIRIN 75/75 mg PD is and what it is used for
2. What you need to know before you take/use CLOPIDOGREL ASPIRIN 75/75 mg PD
3. How to take/use CLOPIDOGREL ASPIRIN 75/75 mg PD
4. Possible side effects
5. How to store CLOPIDOGREL ASPIRIN 75/75 mg PD
6. Contents of the pack and other information

1. What CLOPIDOGREL ASPIRIN 75/75 mg PD is and what it is used for

CLOPIDOGREL ASPIRIN 75/75 mg PD contains the active substances clopidogrel and acetylsalicylic acid (aspirin), 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 in some types of blood vessels, antiplatelet medicines reduce the chances of blood clots forming (a process called atherothrombosis).

CLOPIDOGREL ASPIRIN 75/75 mg PD is used to treat adult patients who have suffered with angina (a severe type of chest pain), or who have had a heart attack, by preventing blood clots, forming and reducing the risk of further atherothrombotic events (such as stroke, heart attack, or death).

2. What you need to know before you take/use CLOPIDOGREL ASPIRIN 75/75 mg PD

Do not take CLOPIDOGREL ASPIRIN 75/75 mg PD:

- if you are hypersensitive (allergic) to clopidogrel, acetylsalicylic acid (aspirin) or to any of the ingredients of CLOPIDOGREL ASPIRIN 75/75 mg PD (see section 6)
- if you are allergic to other medicines called nonsteroidal anti-inflammatory drugs (NSAIDs) usually used to treat painful and/or inflammatory conditions of muscles and joints
- if you have been diagnosed with mastocytosis (a condition where certain immune cells, called mast cells, build up under the skin and/or in the bones) as taking CLOPIDOGREL ASPIRIN 75/75 mg PD may cause a severe hypersensitivity (allergic) reaction
- if you have a history of gastrointestinal bleeding, gastrointestinal ulcer or gastrointestinal perforation related to previous use of an NSAID
- if you have a medical condition that is currently causing bleeding such as a stomach ulcer, haemophilia or bleeding within the brain or bowel or a history of such a condition
- if you are under the age of 18 years
- if you have a medical condition that includes the combination of asthma, nasal discharge (runny nose) and polyps (a type of growth in the nose)
- if you have a medical condition that is currently causing bleeding such as a stomach ulcer, haemophilia or bleeding within the brain or bowel or a history of such a condition
- if you have heart problems which can cause shortness of breath or ankle swelling (heart failure)
- if you suffer from severe liver disease

- if you suffer from severe kidney disease
- if you suffer from a dysfunction of, or reduction in, blood platelets which increases risk of bleeding and bruising (thrombocytopenia)
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with CLOPIDOGREL ASPIRIN 75/75 mg PD:

Inform your doctor or healthcare provider before taking CLOPIDOGREL ASPIRIN 75/75 mg PD if any of the following apply to you, 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 start retaining fluid (symptoms include swelling of feet, ankles and hands, stiff joints, rapid weight gain over a few days or weeks, unexplained weight fluctuations, when pressed, the skin may hold the indent for a few seconds
- you have had a clot in an artery of your brain (ischaemic stroke) which occurred in the last seven days
- you have a history of asthma or allergic reactions including allergy to any medicine used to treat your disease
- if you have a history of heart problems which can cause shortness of breath or ankle swelling (heart failure) or high blood pressure
- you at risk of bleeding, including:
    - 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 7 days
  - a planned spinal, epidural anaesthetic or lumbar puncture in the next 7 days
- you have gout
- you drink alcohol, because of the increased risk of bleeding or gastrointestinal injury
- you have a condition known as glucose-6-phosphate dehydrogenase (G6PD) deficiency because of the risk of a particular form of anaemia (low number of red blood cells)
- you have a history of inflammation of the colon which causes abdominal pain or diarrhoea or any other gastrointestinal conditions
- you are taking any other type of medication (see Other medicines with CLOPIDOGREL ASPIRIN 75/75 mg PD)
- you are a CYP2C19 poor metaboliser (you have very little or no function of the CYP2C19 enzyme, used to break down medicines, in your body)
- you are taking water tablets (used to treat high blood pressure and swelling associated with heart failure, renal failure, or liver disease)
- you are hypersensitive (allergic) to other antiplatelet medicines used to prevent clots (such as ticlopidine or prasugrel)
- you have kidney or liver disease.

Before surgery is planned (including dental), inform your doctor and anaesthetist that you are taking CLOPIDOGREL ASPIRIN 75/75 mg PD.

Inform your doctor immediately should you develop any stomach or abdominal pain or bleeding in the stomach or bowels (red stools or black stools) whilst taking CLOPIDOGREL ASPIRIN 75/75 mg PD.

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 or 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 before or during treatment.

Children and adolescents

CLOPIDOGREL ASPIRIN 75/75 mg PD is not intended for use in children or adolescents younger than 18 years of age. There is a possible association between acetylsalicylic acid (ASA) and Reye's Syndrome when products containing ASA are given to children or adolescents with a viral infection. Reye's Syndrome is a very rare disease which can be fatal.

Other medicines and CLOPIDOGREL ASPIRIN 75/75 mg PD

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
Some other medicines may influence the use of CLOPIDOGREL ASPIRIN 75/75 mg PD or vice versa.

Inform your doctor if you take any of the following:

- medicine that may increase your risk of bleeding such as:
    - oral anticoagulants, thrombolytics, medicines used to reduce blood clotting
    - aspirin or another nonsteroidal anti-inflammatory medicine usually used to treat painful and/or inflammatory conditions of muscle or joints
    - heparin or any other injectable medicine used to reduce blood clotting
    - ticlopidine or prasugrel or other antiplatelet medicines used to reduce blood clotting
    - a selective serotonin reuptake inhibitor (SSRI) (e.g. fluoxetine or fluvoxamine), medicines usually used to treat depression
    - rifampicin (used to treat severe infections)
- omeprazole, esomeprazole or cimetidine, medicines to treat upset stomach or to prevent gastric reflux (heartburn)
- methotrexate, a medicine used to treat severe joint disease (rheumatoid arthritis) or skin disease (psoriasis)

- probenecid, benzbromarone, or sulfinpyrazone, medicines used to treat gout
- fluconazole, voriconazole, ciprofloxacin or chloramphenicol, medicines to treat bacterial and fungal infections
- moclobemide, a medicine to treat depression
- nicorandil, a medicine to treat cardiac chest pain
- repaglinide, a medicine to treat diabetes
- paclitaxel, a medicine to treat cancer
- metamizole, a medicine to treat pain, muscle spasms and fever
- corticosteroids, used to treat inflammation (such a cortisone, prednisolone, hydrocortisone)
- acetazolamide, a medicine to treat glaucoma
- the varicella vaccine, a medicine to prevent chickenpox or shingles, within 6 weeks of taking CLOPIDOGREL ASPIRIN 75/75 mg PD, or if you have an active chickenpox or shingles infection
- levothyroxine, a medicine to treat low thyroid activity
- valproic acid, valproate and carbamazepine, medicines to treat some forms of epilepsy
- tenofovir, an antiretroviral medicine used in the treatment of human immunodeficiency virus (HIV)
- rosuvastatin (used to lower your cholesterol level)
- opioids: while you are treated with clopidogrel, you should inform your doctor before being prescribed any opioids (used to treat severe pain, e.g. morphine).

Alcohol: The consumption of alcohol may affect how well CLOPIDOGREL ASPIRIN 75/75 mg PD works; it may increase blood loss and stomach irritation. Please ask your doctor for more information. Alcohol should be used with caution if you are taking CLOPIDOGREL ASPIRIN 75/75 mg PD.

You should stop other clopidogrel treatments and talk to your doctor before taking any other aspirin containing medicines while you are taking CLOPIDOGREL ASPIRIN 75/75 mg PD.

CLOPIDOGREL ASPIRIN 75/75 mg PD with food and drink

CLOPIDOGREL ASPIRIN 75/75 mg PD can be taken with or without food.

Alcohol should be used with caution if you are taking CLOPIDOGREL ASPIRIN 75/75 mg PD (see Other medicine with CLOPIDOGREL ASPIRIN 75/75 mg PD).

Pregnancy, breastfeeding and fertility

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using CLOPIDOGREL ASPIRIN 75/75 mg PD.

You should not take CLOPIDOGREL ASPIRIN 75/75 mg PD if you are pregnant or breastfeeding your baby (see section 2).

Fertility:

There are no fertility data with clopidogrel/acetylsalicylic acid.

Driving and using machines

CLOPIDOGREL ASPIRIN 75/75 mg PD should not affect your ability to drive or to use machines.

It is not always possible to predict to what extent CLOPIDOGREL ASPIRIN 75/75 mg PD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CLOPIDOGREL ASPIRIN 75/75 mg PD affects them.

CLOPIDOGREL ASPIRIN 75/75 mg PD contains lactose and castor oil

CLOPIDOGREL ASPIRIN 75/75 mg PD contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CLOPIDOGREL ASPIRIN 75/75 mg PD.

CLOPIDOGREL ASPIRIN 75/75 mg PD contains hydrogenated castor oil which may cause stomach upset and diarrhoea.

3. How to take/use CLOPIDOGREL ASPIRIN 75/75 mg PD

Do not share medicines prescribed for you with any other person. Always use CLOPIDOGREL ASPIRIN 75/75 mg PD exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Adults*:*

The usual dose is 1 tablet of CLOPIDOGREL ASPIRIN 75/75 mg PD per day to be taken orally with a glass of water, with or without food.

You should take your medicines at the same time each day.

You should take CLOPIDOGREL ASPIRIN 75/75 mg PD for as long as your doctor continues to prescribe it.

Children:

CLOPIDOGREL ASPIRIN 75/75 mg PD is not prescribed for children.

Your doctor will tell you how long your treatment with CLOPIDOGREL ASPIRIN 75/75 mg PD will last. Do not stop treatment early.

If you have the impression that the effect of CLOPIDOGREL ASPIRIN 75/75 mg PD is too strong or too weak, tell your doctor or pharmacist.

If you take/use more CLOPIDOGREL ASPIRIN 75/75 mg PD than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget/use to take CLOPIDOGREL ASPIRIN 75/75 mg PD

If you forget to take CLOPIDOGREL ASPIRIN 75/75 mg PD, but remember within 12 hours of your usual time, take your tablet straight away 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 forgotten individual doses.

If you stop taking/using CLOPIDOGREL ASPIRIN 75/75 mg PD

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

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

4. Possible side effects

CLOPIDOGREL ASPIRIN 75/75 mg PD can have side effects.

Not all side effects reported for CLOPIDOGREL ASPIRIN 75/75 mg PD are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using CLOPIDOGREL ASPIRIN 75/75 mg PD, please consult your healthcare provider for advice.

The most frequent side effect which has been seen with CLOPIDOGREL ASPIRIN 75/75 mg PD 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 CLOPIDOGREL ASPIRIN 75/75 mg PD:

If you cut or injure yourself, it may take slightly longer than usual for bleeding to stop. This is linked to the way CLOPIDOGREL ASPIRIN 75/75 mg PD works as it prevents the ability of blood clots to form. For minor cuts and injuries e.g. cutting yourself or shaving, this is usually of no concern. However, if you are concerned by your bleeding, you should contact your doctor straight away (see section 2).

If any of the following happens, stop using CLOPIDOGREL ASPIRIN 75/75 mg PD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- 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) – se section 2
- chest pain that may radiate to the neck or left arm, pallor, sweatiness, nausea, breathlessness, low blood pressure. These symptoms may be signs of heart problems due to an allergy to clopidogrel or aspirin (Kounis syndrome)
- sudden severe headache, seizures with no previous history of seizures, weakness in your arm or leg, nausea or vomiting (severe and continuing), sudden tiredness, difficulty speaking or understanding speech, loss of balance, hand tremors or loss of consciousness. These symptoms may be signs of life-threatening bleeding within your skull
- tightness in the chest, wheezing, coughing or difficulty breathing, fatigue
- blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet) with or without a rash. You may also have flu-like symptoms at the same time, such as fever, chills or aching muscles, rash, facial swelling, enlarged lymph nodes and kidney or liver injury. These may be signs of serious skin disorders such as Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN) and drug reaction with

eosinophilia and systemic symptoms (DRESS).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CLOPIDOGREL ASPIRIN 75/75 MG PD. 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 rare decrease of some blood cells (agranulocytosis, granulocytopenia)
- signs of liver problems such as yellowing of the skin and/or the eyes (jaundice, liver failure, hepatitis, liver injury)
- hallucinations (seeing and hearing things that are not there), confusion
- shortness of breath, fatigue, swollen legs and rapid heartbeat (symptoms of cardiac failure)
- reduction in the number of your red blood cells (anaemia) – symptoms may include that you feel weak and tired, and looking pale and that you are more susceptible to infections and uncontrolled bleeding (aplastic anaemia)
- bleeding (including nose bleeds) or bruising more easily than normal. Signs of bleeding may include unusually heavy bleeding from cuts and wounds, coughing up blood, blood in the urine, vomiting of blood or vomit that looks like coffee grounds, bloody or black bowel motions, unusually heavy or unexpected menstrual bleeding, bleeding in the eyes
- reduction in your red and white blood cells and blood platelets (aplastic anaemia) – symptoms may include that you feel weak and tired, and that you are more susceptible to infections and uncontrolled bleeding
- a serious skin reaction called acute generalized exanthematous pustulosis (AGEP) – symptoms may include a red, scaly widespread rash with bumps under the skin (including your skin folds, trunk, and upper extremities) and blisters filled with white/yellow fluid accompanied by fever

- inflammation of the pancreas with symptoms such as severe upper abdominal pain, the abdominal pain may radiate to your back, nausea, vomiting, diarrhoea, tenderness when touching your abdomen, fever
- lung problems called non-cardiogenic pulmonary oedema causing a fluid build-up in the lung – symptoms may include dry cough, fever, difficulty breathing when lying down, chest pain, shortness of breath
- a condition where a certain type of white blood cell called eosinophils accumulates in your lungs (eosinophilic pneumonia) - symptoms may include fever, chest pain worsened by deep breathing, shortness of breath, cough and generally feeling unwell
- low blood sugar (hypoglycaemia) – symptoms may include feeling shaky, anxious or nervous, light-headed, dizzy, chills, sweating or clammy skin, fast heartbeat
- insulin autoimmune syndrome a condition which can cause persistent low blood sugar levels
- increase in blood pressure (hypertension)
- decrease in blood pressure (hypotension)
- severe abdominal pain, with or without back pain, worsening of inflammation of the colon (colitis) which causes abdominal pain and diarrhoea
- ulcer perforation (where an ulcer burns through the stomach or duodenal wall, causing severe, sharp abdominal pain)
- inflammation of your blood vessels with symptoms such as fever, headache, tiredness, weight loss, general aches and pains, night sweats, rash or nerve problems such as numbness or weakness
- presence of blood in urine, kidney failure or inflammation of the kidneys – symptoms may include swelling of legs, ankles, feet or face due to fluid retention, reduction in your urine output, shortness of breath, fatigue, confusion
- fever.

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:

- abdominal pain, indigestion, diarrhoea
- bleeding in the digestive tract (mouth to anus)
- bruising
- bleeding at puncture site
- vomiting, nausea, constipation, excessive gas in stomach or intestines, gastritis (an inflammation of the stomach lining).

Less frequent side effects:

- eye bleeding, broken blood vessels in the eye, bleeding in the retina
- vertigo (loss of balance, spinning sensation)
- rash, itching, rash of purple spots on the skin caused by internal bleeding from small blood vessels.

The following side effects have been reported but the frequency for them to occur is not known:

- taste disturbances, loss of taste
- hives, eczema, purplish, itchy, flat-topped bumps or lacy, white patches, sometimes with painful sores in the mouth
- arthritis, joint pain, muscle pain
- abnormal urine test results
- enlarged breasts in men
- gout
- hearing loss, ringing in the ears
- oedema – swelling caused by fluid trapped in your body's tissues (mainly in the feet, legs and ankles).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

By reporting side effects, you can help provide more information on the safety of CLOPIDOGREL ASPIRIN 75/75 mg PD.

5. How to store CLOPIDOGREL ASPIRIN 75/75 mg PD

Store all medicines out of reach of children.

Store at or below 25 °C, in a cool, dry place.

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CLOPIDOGREL ASPIRIN 75/75 mg PD contains

The active ingredients are clopidogrel hydrogen sulphate equivalent to clopidogrel 75 mg and acetylsalicylic acid (ASA) (aspirin) 75 mg.

The other ingredients are:

Tablet core:

Colloidal hydrated silica, hydrogenated castor oil, hydroxypropyl cellulose, iron oxide yellow, mannitol, microcrystalline cellulose, polyethylene glycol, stearic acid.

Film coating (Opadry ll yellow:

Hypromellose, iron oxide yellow, lactose monohydrate, titanium dioxide, triacetin.

What CLOPIDOGREL ASPIRIN 75/75 mg PD looks like and contents of the pack

Yellow coloured, oval shaped, film coated tablets debossed with “I” on one side and plain on the other side.

CLOPIDOGREL ASPIRIN 75/75 mg PD tablets are available in:

Alu-Alu blister packs packed in a printed outer carton.

Pack sizes: 30

Holder of Certificate of Registration

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This leaflet was last revised in

Registration date: 30 September 2025

Registration number

A58/8.2/0137