

BIODOGREL TABLET 75MG ®

Clopidogrel Besylate 75mg

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What *Biodogrel Tablet 75mg* is used for

Biodogrel Tablet 75mg is used to prevent atherothrombosis (blood clots form in hardened vessels) events if you:

- Had a recent heart attack (myocardial infarction) or previous stroke, or
- Have a condition which causes disturbed blood flow in arms or legs due to blockade of the blood vessels (peripheral arterial disease).

How *Biodogrel Tablet 75mg* works

Biodogrel Tablet 75mg contains the active substance clopidogrel, a platelet aggregation blocker. Platelets are very small structures which clump together (aggregate) during blood clotting. By preventing formation of blood clots (thrombi) in hardened blood vessels, clopidogrel reduces the risk of stroke or heart attack.

Before you use *Biodogrel Tablet 75mg*

- When you must not take it

- If you are allergic (hypersensitive) to Clopidogrel or any of the other ingredients of *Biodogrel Tablet 75mg* (listed in section 'Product description - Ingredients').
- If you have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding within the brain.
- If you have severe liver impairment.

Do not take *Biodogrel Tablet 75mg* if:

Pregnancy and lactation

It is not recommended to use this medicine during pregnancy.

If you are pregnant or think you might be pregnant, tell your doctor before treatment start. If you become pregnant while taking *Biodogrel Tablet 75mg*, tell your doctor immediately.

Do not take *Biodogrel Tablet 75mg* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

You should stop breast-feeding while taking *Biodogrel Tablet 75mg* as it is not known if Clopidogrel passes into breast milk.

- Before you start to take it

Take special care with *Biodogrel Tablet 75mg*:

Check with your doctor or pharmacist **before** taking *Biodogrel Tablet 75mg* if you have poor kidney or liver function, excessive alcohol intake, or are breast-feeding.

Tell your doctor before you start taking this medicine if you are at increased risk of bleeding (haemorrhage), such as:

- Any condition (e.g. stomach ulcer) or blood disorder that makes you prone to internal bleeding (inside tissues, organs)
 - Recent serious injury
 - Surgery (including dental), recent or due in the next 7 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
- Clopidogrel is not intended for use in children or adolescents less than 18 years of age.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or recently used or any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

This applies specially to medicines containing any of the following active substances: (which may increase the risk of bleeding):

- Oral anticoagulants (warfarin and other blood thinners), which should not be used together with *Biodogrel Tablet 75mg*.
- Heparin, Glycoprotein IIb/ IIIa inhibitors like abciximab, eptifibatide, tirofiban and other medicines used to prevent blood clotting
- Thrombolytic agent, such as Alteplase and streptokinase, used to break down blood clots.
- Concomitant use of proton pump inhibitors (medicines used for gastric problem) should be discouraged.
- Non-steroidal anti-inflammatory drugs (NSAIDs), used to treat fever, pain and inflammation of muscles or joints (e.g. ibuprofen, diclofenac, naproxen).

Acetylsalicylic acid (Aspirin, an NSAID) may be used if prescribed, or occasionally up to 1000 mg in 24 h. However, discuss with your doctor its prolonged use in other circumstances.

How to use *Biodogrel Tablet 75mg*:

- How much to use

Follow all directions given to you by doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The usual dose is one 75 mg tablet daily, every day at the same time.

- When to use it

Use as directed by your doctor or pharmacist.

Take one tablet with water after taking food at the same time everyday.

- How long to use it

Continue taking *Biodogrel Tablet 75mg* for as long as your doctor recommends.

Do not stop the treatment or change the dose without discussing it with your doctor first.

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

- If you forget to use it.

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you forget to take *BioDogrel Tablet 75mg*, but remember within 12 hours of your usual time, take your tablet straightaway. Then take your next tablet at the usual time.

If you forget for more than 12 hours, skip the missed dose. Then take the next tablet at the usual time.

Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Contact your doctor or the nearest emergency department immediately because of the increased risk of bleeding.

While you are using it

- Things you must do

You can take *BioDogrel Tablet 75mg* with food or without food.

Take your medicine exactly as your doctor has told you.

Tell the doctors, dentists and pharmacist treating that you are taking *BioDogrel Tablet 75mg*.

Tell your doctor immediately if you become pregnant while taking this medication.

Tell your doctor immediately if you encounter fever, bruising under the skin that may appear as red pinpoint dots (Thrombocytopenic Purpura, TTP).

- Things you must not do

Do not stop taking the medicines unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *BioDogrel Tablet 75mg* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

BioDogrel Tablet 75mg is unlikely to affect your ability to drive or use machines.

BioDogrel Tablet 75mg contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Side effects

Like all medicines, *BioDogrel Tablet 75mg* can cause side effects, although not everybody gets them.

If you notice any of the following very rare serious side effects, contact your doctor immediately:

- Decrease of some blood cells: fever, signs of infection or extreme tiredness.
- Liver problems: yellowing of the skin and/or the eyes (jaundice), bleeding under the skin as red pinpoint dots, confusion.
- Allergic reactions: swelling in the mouth, skin rash, itching and blistering.

A very common side effect is bleeding, which may appear as:

- Bruising and haematoma (a swelling containing blood)
- Nose bleed, blood in the urine
- Bleeding in the stomach or bowels or less frequently in the eye, head, lung or joints

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.

Other side effects:

Common side effects

- Abdominal pain, indigestion or heartburn
- Diarrhoea

Uncommon side effects

- Headache, dizziness
- Stomach ulcer
- Vomiting, nausea
- Constipation, excessive gas in stomach or intestines

- Skin rash, itching
- Abnormal touch sensation

Rare side effects

- Vertigo (a feeling that you or your surrounding is spinning)

Very rare side effects

- Fever
- Yellowing of the skin and/or the eyes (jaundice)
- Severe abdominal pain with or without back pain, pain in joints or muscles
- Generalised allergic reactions
- Skin blisters and allergy
- Swelling or inflammation in the mouth
- Breathing difficulties, sometimes with cough
- Decrease in blood pressure
- Confusion, hallucinations
- Taste disorders

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03 – 78835550, or visiting the website portal.bpfk.gov.my (Consumers – Reporting)

Storage and Disposal of *BioDogrel Tablet 75mg*

-Storage

Keep in a cool, dry place below 25°C., away from direct sun light.

Keep out of the reach and sight of children.

Do not use *BioDogrel Tablet 75mg* after the expiry date which is stated on the carton and on the blister after EXP.

Do not use *BioDogrel Tablet 75mg* if you notice any visible sign of deterioration.

-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

BioDogrel Tablet 75mg film-coated tablets are pink, round and biconvex. They are supplied in PA/ALL/PVC-Alu blisters packed in cartons containing 30, or 100 film-coated tablets.

- Ingredients

- Active Ingredient

The active substance is Clopidogrel. Each film-coated tablet contains Clopidogrel Besylate 112.10mg equivalent to 75mg Clopidogrel.

- Inactive ingredients

Microcrystalline cellulose, hydroxypropylcellulose (E463), mannitol (E421), crospovidone (type A), citric acid monohydrate, macrogol 6000, stearic acid, talc
Coating: Hypromellose (E464), iron oxide red (E172), lactose monohydrate, triacetin (E1518), titanium dioxide (E171)

- MAL number:

BioDogrel Tablet 75mg -
MAL11060011ACR

Manufacturer

Pharmathen S.A.
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**Product registration holder,
Imported and Distributed by**

Biosis Pharmaceuticals Sdn. Bhd.
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