DEPLATT TABLET

Clopidegrel Bisulfate (75mg)

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What Deplatt is used for

You have been prescribed Deplatt 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, 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.

How Deplatt works

Deplatt contains Clopidogrel and 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).

Before you use Deplatt

When you must not use it

Do not take Deplatt:

- If you are allergic (hypersensitive) to Deplatt or any of the other ingredients of this medicine;
- 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.

Pregnancy and lactation

- Do not take Deplatt if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Deplatt, stop taking it immediately and contact your doctor.
- Do not take Deplatt if you are breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

You should tell your doctor 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).
- You have kidney or liver disease.

- Taking other medicines

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

Some medicines and Deplatt may interfere with each other. These include:

- Medicines that thin the blood. The most common examples of these include heparins and warfarin.
- Non-steroidal anti-inflammatory drugs (NSAIDs) medicines used to treat arthritis, period pain, aches and pains.
- Medicines used to treat stomach ulcers or reflux disease (also called heartburn).
- Phenytoin a medicine used to treat epilepsy.
- Tolbutamide a medicine used to treat diabetes.
- Tamoxifen a medicine used to treat breast cancer
- Fluvastatin a medicine used to lower cholesterol.
- Medicines used to prevent gastric reflux proton pump inhibitors (e.g. omeprazole).

How to use Deplatt

- How much to use
- The usual dose of Deplatt is one 75 mg tablet daily.
- A starting dose for chest pain and heart attack is 300 mg and then continued at 75 mg once a day.

- When to use it

Continue taking Deplatt for as long as your doctor recommends".

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

- How long to use it

Use as directed by 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.
- Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. 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.
- Symptoms of overdose includes vomiting, prostration (weakness), difficult breathing, and gastrointestinal bleeding.

While you are using it

- Things you must do
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking Deplatt.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Tell your doctor immediately if you are injured while taking Deplatt.
- Tell all your doctors, dentists, nurses and pharmacists that you are taking Deplatt.

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- Deplatt may increase the risk of bleeding during an operation or some dental work. Therefore, treatment may need to be stopped before surgery.
- Things you must not do
- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Deplatt to anyone else, even if they have the same symptoms or condition as you.
- Things to be careful of

Driving and using machines
This medicine may affect your ability
to drive or use machines. If the tablets
make you feel sick, dizzy or tired, or
give you a headache, do not drive or
use machines and contact your doctor
immediately.

Side effects

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

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

- Accidental injury
- Influenza like symptom
- Pain
- Fatigue
- Edema (swelling caused by excess fluid trapped in the body's tissues)
- Hypertension (high blood pressure)
- Headache
- Nausea
- Dizziness
- Diarrhoea
- Indigestion
- Fever
- Arthralgia (joint pain)
- Back pain
- Itching
- Sensation of tingling and numbness
- Pain or stiffness in the joints
- Rashes
- Skin ulceration
- Red or purple spots visible through your skin
- Nose bleed
- Liver disorder
- Conjunctivitis (inflammation or redness of the lining of the white part of the eye and the underside of the eyelid)
- Problems with coordination
- Cardiac (heart) failure
- Gout

- Respiratory tract infection
- Coughing or difficulty breathing
- Abdominal pain
- Vomiting
- Constipation
- Syncope (loss of consciousness)
- Palpitation
- Anxiety
- Insomnia
- Bleeding may occur as bleeding in the stomach or bowels
- Bruising
- Haematoma (unusual bleeding or bruising under the skin)

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 Clopilet

- Storage
- Keep out of the reach and sight of children.
- Store below 30°C.
- Protect from light and moisture

- 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

Light pink colored, round, bevelled edge, biconvex film coated tablets plain on both sides.

- Ingredients
 - Active ingredient(s)
- Clopidogrel bisulfate
 - Inactive ingredients
- Lactose and MCC
- Mannitol
- Low substituted Hydroxy-propyl
- Cellulose
- Polyethylene Glycol-6000
- Hydrogenated castor oil
- Magnesium Stearate
- Colloidal Silicon Dioxide
- Hypromellose 2910
- Ferric oxide red
- Titanium dioxide

- Methylene chloride
- Isopropyl alcohol
- <u>MAL number(s):</u> MAL10043690A

Manufacturer

Torrent Pharmaceuticals Ltd. Indrad 382 721, District: Mehsana INDIA.

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn Bhd.,

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Date of revision

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