

# CLOPILET TABLET

Clopidogrel 75mg

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## What *Clopilet* is used for

*Clopilet* is used to prevent blood clots forming in hardened blood vessels because you have:

- hardened arteries
- previously experienced heart attack, stroke or a condition known as peripheral arterial disease
- severe chest pain called unstable angina or myocardial infarction.

## How *Clopilet* works

*Clopilet* is a potent inhibitor of platelet aggregation. Platelets are very small structures in the blood, smaller than red or white blood cells, which clump together during blood clotting. By inhibiting platelet aggregation, *Clopilet* prevent or reduce the chances of blood clots forming (a process called thrombosis).

## Before you use *Clopilet*

### When you must not use it:

Do not use *Clopilet*:

- If you are allergic to *Clopilet* or any of the substances contained in the tablet.
- If you have a medical condition that is causing bleeding, such as a stomach ulcer.
- If you have liver problem
- If you are pregnant or breast feeding

### Before you start to use it

*Clopilet* should be used with caution if you have potential risk of increased bleeding from recent trauma, surgery or other pathological conditions.

### 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.

*Clopilet* will interact with some medicine such as:

- Non-Steroidal Anti Inflammatory Drugs (Use for Pain, Inflammation and fever.)
- Phenytoin (Used in fits/epilepsy)
- Warfarin (A blood thinning agent)
- Tamoxifen (Anticancer)
- Tolbutamide (Antidiabetic)
- Tormeside (Used in high blood pressure)
- Fluvastatin (Used in high cholesterol)

## How to use *Clopilet*

### How much to use

Follow all directions given to you by your 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.

Adults and Elderly:

*Clopilet* should be given as a single daily dose of 75 mg with or without food.

If you have had chest pain or a heart attack, a one-time 300 mg dose may be administered followed by one 75 mg tablet daily.

*Children and Adolescents:*

*Clopilet* is not recommended for children or adolescents below 18 years of age.

### When to use it

Use as directed by your doctor or pharmacist.

### How long to use it

Continue taking *Clopilet* for as long as your doctor recommends.

### 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. Taking too many tablets may lead to prolonged bleeding time and subsequent bleeding complications. Appropriate therapy should be considered if bleedings are observed.

## 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 *Clopilet*.

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

If you have a planned elective surgery, *clopilet* has to be discontinued 7 days prior to surgery. Please inform your doctor or pharmacist so that they will do the dosage adjustment for you.

### 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 *Clopilet* 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, *Clopilet* can cause side effects. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Below are some recorded side effect mentioned:

### *Central and Peripheral Nervous System Disorders:*

Headache, dizziness, paraesthesia (abnormal sensations) and vertigo (sudden sensation that like surrounding is spinning).

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## *Gastrointestinal System Disorders:*

Diarrhoea, abdominal pain and dyspepsia (impaired digestion). Gastric ulcer and duodenal ulcer, gastritis, vomiting, nausea, constipation and flatulence.

## *Platelet, Bleeding and Clotting Disorders:*

Bleeding time increased and platelets decreased (Platelets responsible for clotting).

## *Skin and Appendages Disorders:*

Rash and pruritus (severe itching of the skin).

## *White Cell and RES Disorders:*

Leucopaenia (reduction of white blood cell in blood), neutrophils (a neutrophilic white blood cell) decreased and eosinophilia (increased of eosinophils, a type of white blood cell).

## *Post-Marketing Experience:*

Bleeding is the most common reaction reported in the post-marketing experience and was mostly reported during the 1st month of treatment.

## *Bleeding:*

Some cases were reported with fatal outcome especially bleeding in the brain and abdomen.

Serious cases of skin bleeding (purpura), musculoskeletal bleeding (haemarthrosis, haematoma), eye bleeding (conjunctival, ocular, retinal), bleed from the nose, respiratory tract bleeding (haemoptysis, pulmonary haemorrhage), haematuria (presence of blood in urine) and bleeding of operative wound have been reported.

Cases of serious haemorrhage have been reported in patients taking *Clopilet* concomitantly with acetylsalicylic acid and heparin.

## *Blood and Lymphatic System Disorders:*

Thrombotic thrombocytopenic purpura (clotting in small blood vessels of the body), severe thrombocytopenia (lower platelet level that increase the risk of bleeding), deficiency or low level of granulocyte, a type of white blood cell in the blood, aplastic anaemia (deficiency of red blood cells that caused by failure of bone marrow development), pancytopenia (deficiency of all three red cells, white cells, and

platelets) and anaemia (A condition in which the blood doesn't have enough healthy red blood cells).

## *Immune System Disorders:*

Anaphylactoid reactions (life-threatening allergic reaction) and serum sickness (a reaction that is similar to an allergy).

## *Psychiatric Disorders:*

Confusion and hallucinations.

## *Nervous System Disorders:*

Taste disturbances.

## *Vascular Disorders:*

Vasculitis (inflammation of a blood vessel) and hypotension (low blood pressure).

## *Respiratory, Thoracic and Mediastinal Disorders:*

Bronchospasm (causing narrowing and obstruction of the respiratory airway) and interstitial pneumonitis (scarring in both lungs)

## *Gastrointestinal Disorders:*

Inflammation of the pancreas, inflammation of the colon (including ulcerative or lymphocytic colitis) and stomatitis (Inflammation in stomach).

## *Hepatobiliary Disorders:*

Acute liver failure and hepatitis (inflammation of the liver).

## *Skin and Subcutaneous Tissue Disorders:*

Angioedema (the rapid swelling in soft tissues), blistering or reddening (erythema multiforme, Stevens Johnson Syndrome, toxic epidermal necrolysis), rash erythematous, urticarial (skin rash notable for pale red), eczema (skin to become inflamed or irritated) and lichen planus (an inflammatory condition of the skin and mucous membranes).

## *Musculoskeletal, Connective Tissue and Bone Disorders:*

Arthralgia (pain in a joint), arthritis (Inflammation of one or more joints) and myalgia (pain in a muscle or group of muscles).

## *Renal and Urinary Disorders:*

Acute inflammation of the kidney.

## *General Disorders and Administration Site Conditions:* Fever.

## *Blood Tests:*

Abnormal liver function test and increased blood creatinine.

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

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](http://portal.bpfk.gov.my) (Consumers → Reporting).

## **Storage and Disposal of Clopilet**

### Storage

Keep out of the reach and sight of children.

Store below 25°C.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

### 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

Salmon colour, circular, biconvex, film coated tablets with break line on one side.

### Ingredients

Active ingredient

Clopidogrel Bisulphate equivalent to Clopidogrel 75mg.

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## Inactive ingredients

Purified Water, Methylene Chloride, Titanium Dioxide, Hydrogenated Castor Oil, Ferric oxide red, Low substituted hydroxypropyl cellulose, Hypromellose, Crospovidone, Hydroxypropyl Cellulose, Microcrystalline Cellulose, Talc, Isopropyl Alcohol, Mannitol, Acetone and Polyethylene Glycol

**MAL number: MAL10120012A**

## Manufacturer

SUN PHARMACEUTICAL

INDUSTRIES LIMITED

Survey No. 214,

Government Industrial Area,

Phase II, Silvassa-396 230. INDIA

## Product Registration Holder

PAHANG PHARMACY SDN. BHD.

Lot 5979 Jalan Teratai, 5 ½ Mile Off

Jalan Meru, 41050 Klang, Selangor

MALAYSIA

## Date of revision

11/09/2015

## Serial Number

BPFK(R4/1)080915/00305