

TICLID[®]

Ticlopidine 250mg

What is in this leaflet

1. What Ticlid is used for
2. How Ticlid works
3. Before you use Ticlid
4. How to use Ticlid
5. While you are using it
6. Side effects
7. Storage and Disposal of Ticlid
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Ticlid is used for

Ticlid is used for:

- Maintenance of normal blood flow to heart after heart bypass surgery.
- Maintenance of patency of access sites in patients on long term hemodialysis.
- Prevention of blood clot formation following heart intervention procedure (heart stent placement) in combination with other antiplatelet medications such as aspirin.
- Reducing risk of a new stroke in patients who have experienced stroke symptoms and in patients who have had a stroke in the past. Because Ticlid can cause life-threatening blood problems, Ticlid should be reserved for patients who are intolerant or allergic to aspirin therapy or who have failed aspirin therapy.

How Ticlid works

Ticlid contains the active substance ticlopidine. It belongs to a group of medicines called antiplatelet agents. It works by reducing the ability of blood clotting cells (platelet) to stick to each other and to blood vessel walls. This will lessen the ability of blood clots forming in unwanted places such as narrowed blood vessels.

Before you use Ticlid

When you must not use it

Do not take Ticlid if:

- You are allergic (hypersensitive) to ticlopidine and/or any of the other ingredients of Ticlid (listed in section 8 below)
- You have had blood disorders in the past (decrease in the number of white blood cells or decrease in the number of platelets)
- You have any blood diseases with prolonged bleeding time
- You have any active bleeding problems such as stomach ulcer or bleeding inside the brain due to rupture of vessel.
- You have an abnormal tendency to spontaneous often severe bleeding (bleeding diathesis)

Do not take if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Ticlid.

Before you start to use it

Take special care and check with your doctor or pharmacist if:

- You are about to have an operation
- You have an increase risk in bleeding
- You are taking anticoagulants or platelets aggregation inhibitors such as aspirin and non-steroid anti-inflammatory drugs. However, when used in patients with heart stent placement, ticlopidine is taken with aspirin (100-325mg/day) for a duration of about one month following placement.
- You have liver problems.

Ticlid can cause some problems with your blood, liver and some serious allergic reactions. (see possible side effects)

Your doctor will carry out blood tests before you start taking Ticlid and every two weeks for the first three months of treatment to monitor your blood cells including platelets.

Taking other medicines

Do not take this medicine and tell your doctor if you are taking:

- Acetylsalicylic acid also known as aspirin- used to relieve pain, fever, inflammation and prevent formation of blood clot.

The following medicines need extra precautions for use in combination with Ticlid:

- Ciclosporin- used to help prevent rejection of transplants
- Phenytoin and fosphenytoin- used to treat epilepsy
- Theophylline and aminophylline- used to treat wheezing and other breathing difficulties.

The following medicines can increase the chance of you getting side effects, when taken with Ticlid:

- Oral anticoagulant
- Heparin- used as an anticoagulant
- Thrombolytics- used to dissolve blood clots.

As a precaution, Ticlid should preferably not be administered during pregnancy and lactation.

How to use Ticlid

Always take Ticlid exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow your tablets orally in whole with a glass of water.
- This medicine need to be taken with food.

How much to use

Adults

- The usual dosage for all indications is 1 tablet (250mg) twice a day.

When to use it

Take Ticlid at about the same time each day unless your doctor tells you otherwise.

Taking your medicine at the same time each day will have the best effect. It

will also help you remember when to take the medicine.

If you are not sure when to use it, ask your doctor or pharmacist.

How long to use it

Continue taking your medicine for as long as your doctor tells you.

If you forget to use it

- If you forget to take your tablet, leave out that dose completely and take the next tablet at the usual time.

- Do not take a double dose to make up for a forgotten tablet.

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

If you use too much (overdose)

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately. Take the medicine pack with you. Severe stomach/intestinal upset may happen.

While you are using it

Things you must do

- Inform your doctor immediately if you have fever, sore throat or mouth sores and/ or unusual or prolonged bleeding, blackish/bloody stool, dark urine, light-colored stools and jaundice.
- Tell your doctor immediately if you are pregnant or become pregnant during your treatment.
- Ticlid can be found in breast milk. Tell your doctor if you are breastfeeding.
- If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Things you must not do

- **Do not give this medicine to anyone else, even if they have the same condition as you.**
- **Do not use this medicine to treat any other complaints unless your doctor tells you to.**
- **Do not stop taking Ticlid, or change the dosage, without checking with your doctor.**

Things to be careful of

Driving and using machines

You can drive or use any tools or machines. If you are affected by the following side effects, **do not drive or use machines.**

Side Effect

Like all medicines, Ticlid can cause side effects, although not everyone gets them.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Some of the reported possible side effects are:

- Decrease in the number of white blood cells (neutropenia)
- Diarrhea, nausea
- Peri- and post-operative bleeding
- Skin rashes (urticaria or maculopapular) often accompanied by itching
- An increase in some liver test results (during first 4 months of treatment)
- An increase in the levels of fat in the blood (cholesterol and triglycerides after 1-4 months of treatment with no further elevations subsequently)
- Decrease in the number of blood platelets (thrombocytopenia); decrease in the number of all blood cells (pancytopenia); decrease in production of blood cells by bone marrow (bone marrow aplasia)
- A blood disorder where blood clots form in small blood vessels throughout the body (thrombotic thrombocytopenic purpura)

Very rare side effects

- Severe diarrhea with inflammation of large intestines (lymphocytic colitis)
- Severe sometimes life threatening skin reactions (erythema multiforme)
- An increase in some liver results which may develop into serious conditions such as cytolytic and cholestatic hepatitis.
- Inflammation of small vessels (vasculitis)
- Severe skin allergic reactions (anaphylactic reactions, angioedema)
- Joint and muscle pain, rashes (lupus syndrome)

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 (Consumers → Reporting).

Storage and Disposal of Ticlid

Storage

-Keep out of the reach and sight of children.

-Do not use Ticlid after the expiry date which is stated on the carton and the blister.

-Store in a cool place below 30°C.

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

This film coated tablets are white to off-white, round and biconvex. They are supplied in 20 film coated tablets in blisters of 10 each.

Ingredients:

- The active substance is 250mg ticlopidine hydrochloride.
- The other ingredients are microcrystalline cellulose 90 microns, polyvidone K-30, citric acid anhydrous, stearic acid, magnesium stearate, maize starch.
- For the coating: white opadry (titanium dioxide, hydroxypropylmethyl cellulose, and polyethyleneglycol 8000)

MAL Numbers:

Ticlid Tablets 250mg:
MAL19930512AR

**Manufacturer and Product
Registration Holder**

Manufacturer

Sanofi -Aventis S.A.,
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Product Registration Holder

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Date of revision

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