

APLAKET TABLET 250MG

Ticlopidine hydrochloride 250mg

What is in this leaflet

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

What APLAKET tablet is used for

Aplaket is used to help to prevent the formation of blood clots (Thrombosis). This is to avoid ischemia (reduced blood flow due to blockage) in brain, heart or blood vessels.

Aplaket is used in patients who are at risk of stroke or experienced previous heart attack/stroke. It is also indicated if a patient is intolerable to aspirin or in whom aspirin does not work.

Aplaket can prevent re-occlusion of bypass graft (a heart surgical procedure) and is used in haemodialysis as well.

How APLAKET tablet works

Aplaket contains Ticlopidine, which inhibit platelet (blood clotting cells) to stick to each other and to blood vessel walls and causes prolongation of bleeding time. It causes dose-dependent inhibition of blood clotting.

Before you use APLAKET tablet

When you must not use it

- if you are hypersensitive to ticlopidine.
- if you are affected or have experienced leucopenia (decrease of white blood cells which makes infections more likely), thrombocytopenia (reduction in blood platelets, which increases the risk of bleeding) or agranulocytosis (severe reduction in number of white blood cells which makes infections more likely).
- if you suffer from bleeding diathesis which increase susceptibility to bleeding due to a coagulation defect and haemostatic disorders inducing a prolongation of the bleeding time.
- if you have active pathological bleeding (such as gastrointestinal ulcer, bleeding esophageal varices, etc.); acute haemorrhagic cerebrovascular strokes; severe liver disease.
- if you are pregnant or nursing.

Before you start to use it

- Before starting therapy and, then, every 15 days for the first 3 months of treatment, it is necessary to perform blood cell counting, particularly leucocyte (white blood cell) and platelet counts.
- Before a surgical intervention,

the treatment must be withdrawn for one week (except for those cases who cannot interrupt it) due to the bleeding risk induced by the product; after treatment withdrawal and before the intervention, it is advised to evaluate if the effect on haemostatis still persists (by determination of the bleeding time).

- If a dental extraction is needed, inform the dentist of the treatment in course.

- In the case that pharyngitis (infection of the back of the throat), ulcers of the mouth, angina (chest pain), fever, bleeding or bruising occur, the treatment should be immediately withdrawn and the physician should be informed; the eventual resumption of therapy depends from the results of the blood tests and clinical evaluation.

- Patients with impaired liver function should use APLAKET with caution and should discontinue the treatment if liver inflammation or jaundice develops.

- Safety and efficacy in children below 18 years old have not been established.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. As APLAKET induces a prolongation of bleeding time, its association with NSAIDS (Aspirin, etc), with anticoagulants (heparin, anti-vitamin K), should be avoided. The association with potential bone marrow destructive medicines should be avoided.

APLAKET TABLET 250MG

Ticlopidine hydrochloride 250mg

How to use Aplaket tablet

How much to use

The recommended dose is, for a long-term treatment, 1-2 coated tablets daily.

When to use it

It is recommended to take APLAKET at meals.

How long to use it

Continue taking APLAKET for as long as your doctor recommends.

If you forget to use it

Do not take a double dose to make up for a missed dose. If you have further questions about using this medicine, ask your doctor or pharmacist.

If you use too much (overdose)

If you may have taken more APLAKET than you should, talk to a doctor or pharmacist immediately.

Symptoms of overdosage are: bleeding, convulsions, dangerously low body temperature, shortness of breath, loss of equilibrium and abnormal gait.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you. Tell your doctor immediately if you become pregnant while taking this medication.

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 APLAKET to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

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

The following undesirable effects have been shown in course of treatment with Aplaket:

- bleeding complications, ie very dark or black, tarry stools;
- leucopenia, thrombocytopenia and agranulocytosis (sign of fever, chills, sore throat or mouth ulcers). The severe impairment of bone marrow function is particularly severe in the elderly;
- gastrointestinal discomforts (nausea, gastralgia, diarrhoea);
- increase of liver enzymes and, rarely, cholestatic jaundice (yellowing of the eyes and skin). It is therefore advised to monitor liver function periodically;
- skin rash, which is reversible by withdrawing the treatment;
- vertigo (sensation of spinning characterized by balance impairment);
- bruising or bleeding more easily than normal, bluish-purple spots under the skin or nails.

You should inform your doctor of any other undesirable effect during treatment.

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 APLAKET tablet

Storage:

Store below 25 ° C. Keep the medicine out of the reach of children. Expiry date is 3 years from the date of manufacturing. The expiry date refers to the last day of the 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

Aplaket is a white, round shiny sugar coated tablet.

Ingredients:

Active ingredient: Ticlopidine hydrochloride 250 mg
Inactive ingredient: Lactose monohydrate, sodium starch glycolate, polyethylene glycol, povidone, magnesium stearate, hydroxypropyl cellulose, ethylcellulose, diethyl phthalate, acacia gum, titanium dioxide, talc, sucrose, montanglycol wax.

MAL number:

MAL19988442A.

APLAKET TABLET 250MG

Ticlopidine hydrochloride 250mg

Manufacturer:

Madaus GMBH
Troisdorf, Germany.

Product Registration holder

Antah Pharma Sdn Bhd
No. 3, Jalan 19/1, 46300,
Petaling Jaya, Selangor,
Malaysia.

Date of Revision

06 June 2015.

BPFK(R4/1)100415/00061