

# Ticlopidine Hexal® 250mg

Ticlopidine hydrochloride

Patient Information Leaflet

**Read this entire leaflet carefully before you start taking the medication.**

- Keep this leaflet. You may need to read again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

## WHAT IS IN THIS LEAFLET?

1. What Ticlopidine is used for
2. How Ticlopidine works
3. Before you take Ticlopidine
4. How to take Ticlopidine
5. While you are using Ticlopidine
6. Possible side effects
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## 1. WHAT TICLOPIDINE IS USED FOR

Ticlopidine Hexal is used to help prevent the formation of blood clots. Ticlopidine is used in patients who are at risk of having stroke, or undergoing long term hemodialysis or patients who have undergone heart stent surgery (angioplasty).

## 2. HOW TICLOPIDINE WORKS

Ticlopidine Hexal contains the active ingredient, ticlopidine hydrochloride.

Ticlopidine belongs to the group of medicines called 'platelet aggregation inhibitors'. It work by reducing the ability of blood clotting cells (platelet) to stick to each other and to blood vessel walls. This lessen the ability of blood clots forming in unwanted places such as narrowed blood vessels.

## 3. BEFORE YOU TAKE TICLOPIDINE

### When you must not take it

Do not take Ticlopidine Hexal if you:

- Have ever had allergic reaction to ticlopidine hydrochloride, the active ingredient, or to any other ingredients in Ticlopidine.
- Have severe liver disease or other diseases that may affect your liver,
- Any active bleeding problems such as stomach ulcer or bleeding inside the head (intracranial bleeding)
- Any blood disorder such as low white blood cell count, no white blood cell, or low platelet count,

*If you are not sure whether you should start taking this medicine, consult your doctor.*

### Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- Are pregnant; think you are pregnant or planning to become pregnant,
- Are breast feeding or plan to breast feed,
- Have liver problems,
- Have kidney problems,
- Recently undergo surgery or suffer any injuries.

### Taking / using other medicines

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription.

There may be interference between Ticlopidine and some other medicines including:

- Medicines to treat arthritis, pain and inflammation such as Aspirin and Non-steroidal anti-inflammatory drugs (NSAIDS),

- Other medicines to prevent blood clots such as warfarin, dipyridamole or clopidogrel,
- Injections to prevent blood clots such as heparin, enoxaparin, alteplase or streptokinase.
- Theophylline, a medicine to treat asthma,
- Phenytoin and Phenobarbital, medicines for epilepsy,
- Digoxin, a medicine to treat heart failure,
- Antacid for gastric that contains aluminium and magnesium,
- Cimetidine, a medicine for heart burn or peptic ulcer,
- Propranolol, medicine for high blood pressure from beta-blockers group.

These medicines may be affected by Ticlopidine or may affect how well it works. You may need different amounts of your medicines or take different medicines. Your doctor or pharmacist will have more information on the medicines to be careful with or to avoid while taking Ticlopidine.

### Pregnancy and breast-feeding

Tell your doctor if you are pregnant; think you are pregnant or planning to become pregnant. Your doctor will discuss the risks and benefits of taking Ticlopidine during pregnancy and breastfeeding.

## 4. HOW TO TAKE TICLOPIDINE

Always take Ticlopidine Hexal according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.

The directions given by your doctor may differ from this leaflet.

### How much to take

The usual starting dosage is 1 tablet to be taken twice a day with meals.

### When to take it

Take Ticlopidine at the same time everyday with meals for the best effect and to minimize chance of stomach upset.

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## How long to take it

Continue to take your medicines as long as your doctor tells you.

## If you forget to take it

Just take your next dose at the normal time it is due. Do not take a double dose to make up for the dose you missed or taking more than 1 dose at a time. This may cause unwanted side effects.

## If you take too much (overdose)

If you or anyone else takes too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

Symptoms of overdose include gastrointestinal bleeding, convulsion, hypothermia, breathing difficulty, loss of balance and abnormal walking posture.

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

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## 5. WHILE YOU ARE USING TICLOPIDINE

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### Things you must do

- Always follow your doctor's instruction carefully.
- Tell your doctor immediately if you notice any unusual symptoms.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Ticlopidine.
- If you become pregnant, or plan on becoming pregnant while taking Ticlopidine, tell your doctor immediately.
- Inform any other doctors, dentists and pharmacists who treat you that you are taking Ticlopidine.
- If you plan to have surgery that needs general anesthetic, tell your doctor or dentist that you are taking Ticlopidine.
- If you need to have any other surgical procedure, including dental extraction, tell

your doctor or dentist that you are taking Ticlopidine. Ticlopidine may prolong bleeding in some patient.

- Visit your doctor regularly so that they can check on your progress. You will need to have blood tests before and after you begin to take Ticlopidine.

### Things you must not do

- Do not stop taking Ticlopidine or change the dose without your doctor's permission.
- Do not take Ticlopidine to treat any other complaint unless your doctor tells you to.
- Do not give Ticlopidine to anyone else, even if they have the same condition as you.

### Things to be careful of

Ticlopidine is unlikely to affect your ability to drive or use machinery.

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## 6. POSSIBLE SIDE EFFECTS

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All medicines can have side effects. Ticlopidine may cause unwanted side effects although not everybody gets them.

Tell your doctor or pharmacist if you notice the following side effects and they worry you:

- Gastrointestinal disturbances (nausea, diarrhea)
- Skin rash and itchiness
- Increase liver enzymes
- Increase in cholesterol level

*The above list is the more common side effects of the medicine.*

Tell your doctor immediately or go to nearest hospital if you notice any of the following:

- Signs of bleeding such as:
  - Bruising or bleeding more easily than normal,
  - Bluish-purple spots under skin or nails
  - Very dark or black, tarry stool
- Signs of infection such as fever, chills, sore throat or mouth ulcers
- Allergic reaction such as
  - wheeziness,

- difficulty in breathing,
- swelling of face, lips, or tongue
- rash or itching (especially affecting the whole body),
- Hepatitis or jaundice.

*The above list is the serious side effects of the medicine. You may need urgent medical attention or hospitalization. These side effects are rare.*

**Tell your doctor or pharmacist if you notice anything else that make you feel unwell. Other side effects not listed above may also occur in some people.**

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## 7. AFTER USING TICLOPIDINE

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### Storage

Store in a cool, dry place not above 25°C. Keep in original package to protect from heat, light, and moisture.

Do not store Ticlopidine or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of the reach and sight of children.

### Disposal

Do not use Ticlopidine after the expiry date which is stated on the carton and blister. If your doctors tell you to stop taking Ticlopidine or the expiry date has passed, ask your pharmacist what to do with the remaining medicines.

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## 8. PRODUCT DESCRIPTION

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**What Ticlopidine Hexal® 250mg looks like and contents of the pack.**

Ticlopidine Hexal is a white film-coated tablet.

### Packing

Ticlopidine comes in blister strip of 30 and 90 tablets a box.

### Ingredients

Active ingredient: Each Ticlopidine Hexal 250mg tablet contains 250mg of ticlopidine hydrochloride.

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Other ingredients:

Povidone, colloidal silica anhydrous, magnesium stearate, maize starch, microcrystalline cellulose, and opadry white.

## **Registration Number**

MAL06041477A

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## **9. MARKETING AUTHORISATION HOLDER AND MANUFACTURER**

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### **Manufacturer:**

Salutas Pharma GmbH  
Otto-Von-Guericke-Allee 1,  
D-39179, Barleben, Germany

### **Marketing Authorisation Holder:**

IMEKS Pharma Sdn. Bhd.  
No. 1 & 2, Jalan 6/33B,  
MWE Commercial Park,  
52000 Kuala Lumpur. Malaysia

Date of Revision: Aug 2011