

Tilodene

contains the active ingredient ticlopidine hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Tilodene.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Tilodene against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What Tilodene is used for

Tilodene is used to help prevent the formation of blood clots.

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

Tilodene is used in patients who are at risk of having a stroke. A stroke occurs when a blood clot blocks a blood vessel in the brain.

Tilodene is used in patients who cannot take aspirin or in whom aspirin does not work.

Your doctor may have prescribed Tilodene for another reason. Ask your doctor if you have any questions about why Tilodene has been prescribed for you.

Tilodene is not recommended for use in children, as there have been no studies of its effects in children.

Tilodene is available only with a doctor's prescription.

Before you take Tilodene

When you must not take it

Do not take Tilodene if you are allergic to ticlopidine hydrochloride or any of the ingredients listed at the end of this leaflet.

Do not take Tilodene if you are over 65 years of age and have liver or kidney problems.

Do not take Tilodene if you have any of the following medical conditions:

- * any blood disorder such as a low white blood cell count, no white blood cells or a low platelet count
- * any active bleeding problems such as a stomach ulcer or bleeding inside the head (intracranial bleeding)
- * severe liver disease or cholestatic jaundice
- * severe renal disease which needs dialysis
- * severe heart failure which is also affecting your liver.

If you are not sure whether you should start taking Tilodene, ask your doctor.

Do not take Tilodene if the expiry date (Exp.) printed on the pack has passed.

Do not take Tilodene if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking Tilodene during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking Tilodene when breastfeeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- * liver problems
- * kidney problems
- * stomach ulcers
- * recent surgery or injury
- * high cholesterol levels.

If you have not told your doctor about any of the above, tell them before you start taking Tilodene.

Taking other medicines

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

Some medicines may be affected by Tilodene, or may affect how well it works. These include:

- * heparin, enoxaparin, tinzaparin, or danaparoid, injections used to prevent blood clots
- * warfarin, dipyridamole, clopidogrel, or other drugs which are used to prevent blood clots
- * medicines used to treat arthritis, pain and inflammation, such as aspirin and non-steroidal anti-inflammatory drugs
- * theophylline, a medicine used to treat asthma and other lung conditions
- * digoxin, a medicine used to treat heart failure and other heart problems
- * cimetidine, a medicine commonly used to treat reflux and ulcers
- * antacids
- * carbamazepine and phenytoin, medicines used to treat epilepsy and fits.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Tilodene.

How to take Tilodene

How much to take

The usual dose is one tablet twice a day.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take it

Swallow the tablets with a glass of water.

Take Tilodene with meals.

Taking Tilodene with meals helps reduce the chance of an upset stomach.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take it for

Keep taking Tilodene for as long as your doctor recommends.

Tilodene is usually taken long term to help prevent a stroke.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), if you think you or anyone else may have taken too much Tilodene. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Tilodene

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Tilodene.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Tilodene.

If you become pregnant while taking Tilodene, tell your doctor.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Tilodene.

Tilodene should be stopped about 10 to 14 days before elective surgery.

If you need to have any other surgical procedure, including dental extraction, tell your doctor or dentist that you are taking Tilodene.

Tilodene may cause prolonged bleeding in some patients.

Visit your doctor regularly so that they can check on your progress. You will need to have blood tests before you begin treatment and every two weeks during the first four months that you take Tilodene.

Some patients may develop neutro-penia, a condition where there is a decrease in the number of neutrophils, a type of white blood cell, in the blood. This condition is not common, but if not detected early can lead to severe or life-threatening infections. Regular blood tests help make sure this condition is detected early.

Things you must not do

Do not stop taking Tilodene, or lower the dose, without checking with your doctor. Do not let yourself run out of Tilodene over the holidays or weekends.

Do not use Tilodene to treat any other conditions unless your doctor tells you to.

Do not give Tilodene to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Tilodene affects you.

Tilodene can increase cholesterol levels. If you already have high cholesterol, you may need regular blood tests to check your cholesterol levels.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tilodene.

Like all other medicines, Tilodene may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * nausea (feeling sick), vomiting
- * stomach pain, indigestion
- * diarrhoea
- * loss of appetite
- * skin rash or itchy skin
- * dizziness.

The above list includes the more common side effects of your medicine. They are usually mild.

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

- * dark urine and light-coloured stools, yellowing of the eyes and skin (jaundice)

- * bruising or bleeding more easily than normal, bluish-purple spots under the skin or nails
- * very dark or black, tarry stools
- * signs of infection such as fever, chills, sore throat or mouth ulcers
- * symptoms of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell while you are taking, or soon after you have finished taking Tilodene.

Other side effects not listed above may also occur in some people.

After using Tilodene

Storage

Keep Tilodene where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in a cool dry place where the temperature stays below 25 degrees C.

Do not store Tilodene or any other medicine in the bathroom or near a sink.

Do not leave Tilodene in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Tilodene, or your tablets have passed their expiry date, ask

your pharmacist what to do with any that are left over.

Product description

What it looks like

Tilodene tablets are white to off-white, oval and marked with "G" and "T250".

Tilodene comes in bottles of 60 tablets.

Ingredients

The active ingredient in Tilodene is ticlopidine hydrochloride. Each Tilodene tablet contains 250 mg of ticlopidine hydrochloride.

The tablets also contain:

- * cellulose - microcrystalline
- * povidone
- * starch - maize
- * ammonium chloride
- * stearic acid
- * magnesium stearate
- * Opadry II White Y-30-18037 (includes colour 171).

The tablets are gluten free.

Supplier

Tilodene is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Tilodene - Aust R 73686

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