Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tacidine.

It does not contain all 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 Tacidine 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 Tacidine is used for

Ulcer

Tacidine is used to treat both gastric ulcers and duodenal ulcers. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum (which is a tube leading out of the stomach). The ulcers can be caused in part by too much acid being made in the stomach.

Tacidine is also used to help stop duodenal ulcers from coming back.

Reflux disease

Tacidine is also used to treat reflux oesophagitis or reflux disease. This is caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (also known as the oesophagus).

Reflux causes burning sensation in the chest rising up to the throat (heartburn) and most often occurs after eating or at night.

Tacidine belongs to a group of medicines called histamine H2 antagonist or histamine H2 blockers. These medicines work by reducing the amount of stomach acid produced which in turn reduces the pain and allows the ulcers and/or reflux disease to heal in most people.

Ask your doctor if you have any questions about why Tacidine has been prescribed for you.

Your doctor may have prescribed Tacidine for another reason.

Tacidine is not recommended for use in children, as the safety and effectiveness of Tacidine in children have not been established.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before you take Tacidine

When you must not take it

Do not take Tacidine if you have an allergy to:

- · any medicine containing nizatidine
- any other histamine H2 blocking medicine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- · wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Tacidine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to 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 have or have had any of the following medical conditions:

- · kidney disease
- · liver disease
- · chronic lung disease
- · diabetes
- a weakened immune system or lowered resistance to infection, sometimes caused by certain diseases or treatments.

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

Your doctor can discuss the risks and benefits involved.

Tacidine passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Tacidine when breastfeeding.

Tell your doctor if you plan to have surgery.

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

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 and Tacidine may interfere with each other. These include:

- aspirin
- certain antacids used to treat heartburn and indigestion such as Mylanta and Gelusil.

These medicines may be affected by Tacidine or may affect how well it works. Your doctor can tell you what to do if you are taking any of these medicines.

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

How to take Tacidine

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 pack, ask your doctor or pharmacist.

How much to take

The dose varies from person to person:

- duodenal and stomach ulcers the recommended daily dosage is 150 mg twice daily or 300 mg once in the evening
- to stop duodenal ulcers from coming back the usual dosage is 150 mg once daily
- reflux disease the recommended dosage is 150 mg twice daily.

Elderly people and those who have kidney problems may need lower doses.

How to take it

Swallow the capsules whole with a full glass of water.

When to take it

Take Tacidine at about the same time each day.

This will allow Tacidine to have its best effect and also help you remember when to take it.

Tacidine can be taken with or without food.

The 150 mg capsule is usually taken twice a day one capsule in the morning and one capsule in the evening before you go to bed.

The 300 mg capsule is usually taken once daily at bedtime.

How long to take it

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

Do not stop taking Tacidine, even if you feel better after a few days, unless advised by your doctor.

If you stop taking your medicine too early then your condition will not have been properly treated.

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 it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Tacidine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Tacidine

Things you must do

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Tacidine.

Tell any other doctors, dentists and pharmacists who treat you that you are taking Tacidine.

If you become pregnant while taking Tacidine, tell your doctor immediately.

If you are going to have surgery, including dental surgery, tell your doctor or dentist that you are taking Tacidine.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not use Tacidine to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

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

This medicine may cause dizziness or lightheadedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Things that would be helpful for your condition

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Alcohol your doctor may advise you to limit your alcohol intake.
- Aspirin and many other medicines used to treat arthritis/period pain/headaches - these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist may suggest other medicines you can take
- Caffeine your doctor may advise you to limit the number of drinks which contain caffeine, such as coffee, tea, cocoa and cola drinks, as the caffeine may irritate your stomach.
- Eating habits eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meal times.
- Smoking your doctor may advise you to stop smoking or at least cut down.

Side effects

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

Tacidine is generally well tolerated, however, like all other medicines, Tacidine 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.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

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

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

- sweating
- · itchy skin rash or hives
- · impotence.

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

Tell your doctor immediately if you notice any of the following:

- yellowing of the whites of the eyes or skin, also called jaundice
- dark urine
- breast enlargement/tenderness
- symptoms of anaemia, which may include tiredness, dizziness and looking pale
- bleeding or bruising more easily than normal
- confusion.

The above list includes serious side effects that may require medical attention.

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

- · vomiting blood or food
- · passing black (blood-stained) bowel motions
- symptoms of a severe allergic reaction which may include 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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After taking Tacidine

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

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

Do not leave Tacidine in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep Tacidine 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.

Disposal

If your doctor tells you to stop taking Tacidine, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Tacidine capsules comes in 2 strengths:

- Tacidine 150 hard gelatin capsule where one half of the capsule is pale yellow and has "NZ 150" printed in black. The other half of the capsule is dark yellow and has "G" printed in black.
 - Each blister pack contains 60 capsules.
- Tacidine 300 hard, light brown, gelatin capsule with "NZ 300" printed in black on one half of the capsule and "G" printed in black on the other half.
 Each blister pack contains 30 capsules.

Ingredients

Each Tacidine 150 capsule contains 150 mg of nizatidine.

Each Tacidine 300 capsule contains 300 mg of nizatidine.

The capsule also contains:

- croscarmellose sodium
- · starch pregelatinised maize
- purified talc
- · magnesium stearate
- quinoline yellow CI47005 [E104] (150 mg
- allura red AC CI16035 [E129] (150 mg only)
- iron oxide red CI77491[E172] (300 mg only)
- iron oxide yellow CI77492 [E172]
- titanium dioxide [E171]
- · gelatin
- Black Ink SW-9008/SW-9009.

The capsules are gluten free.

Sponsor

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www.alphapharm.com.au Australian Registration Numbers: Tacidine 150 - AUST R 94204 Tacidine 300 - AUST R 94205

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