

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking TACIDINE?

TACIDINE contains the active ingredient nizatidine. TACIDINE is used to treat reflux oesophagitis or reflux disease, ulcers and to stop duodenal ulcers from coming back.

For more information, see Section [1. Why am I taking TACIDINE?](#) in the full CMI.

2. What should I know before I take TACIDINE?

Do not take TACIDINE if you have ever had an allergic reaction to nizatidine, other histamine H2-receptor antagonists (e.g. cimetidine, ranitidine, famotidine) or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take TACIDINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TACIDINE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take TACIDINE?

Your doctor will tell you how much TACIDINE you need to take each day depending on your condition.

- The 150 mg capsule is usually taken in the morning and in the evening before you go to bed.
- The 300 mg capsule is usually taken once daily, at bedtime.

More instructions can be found in Section [4. How do I take TACIDINE?](#) in the full CMI.

5. What should I know while taking TACIDINE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking TACIDINE. • If you become pregnant while taking this medicine, tell your doctor immediately. • Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	• Do not use this medicine to treat any other complaints unless your doctor tells you to. • Do not give it to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful driving or operating machinery until you know how TACIDINE affects you. • TACIDINE may cause dizziness or light-headedness in some patients. Make sure you know how you react before driving a car or operating machinery.
Drinking alcohol	• Your doctor may advise you to limit your alcohol intake while you are being treated for your condition.
Looking after your medicine	• Keep your capsules in a cool dry place where the temperature stays below 25°C. • Keep the capsules in their blister pack until it is time to take them.

For more information, see Section [5. What should I know while taking TACIDINE?](#) in the full CMI.

6. Are there any side effects?

Common side effects: sweating, itchy skin rash or hives, headaches, flatulence, vomiting, diarrhoea or constipation. **Serious side effects:** yellowing of the whites of the eyes or skin, dark urine, tiredness, dizziness and looking pale or confusion. **Very serious side effects:** vomiting blood or food, passing black bowel motions or 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. **This is not a complete list of all possible side effects.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TACIDINE®

Active ingredient: *nizatidine*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking TACIDINE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking TACIDINE.**

Where to find information in this leaflet:

1. [Why am I taking TACIDINE?](#)
2. [What should I know before I take TACIDINE?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take TACIDINE?](#)
5. [What should I know while taking TACIDINE?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking TACIDINE?

TACIDINE contains the active ingredient nizatidine.

Nizatidine belongs to a group of medicines called H2-antagonist or H2-blockers. These medicines work by reducing the amount of acid in your stomach. This helps reduce the pain and allows the ulcer and reflux disease to heal in most people.

TACIDINE is used to treat the following conditions:

- **Reflux oesophagitis or reflux disease.** This can be caused by “washing back” (reflux) of food and acid from the stomach into the food pipe. Reflux can cause a burning sensation in the chest rising up to the throat (heartburn), and most often occurs after eating or at night.
- **Ulcers.** 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 the tube leading out of the stomach (which is part of your small intestine). Ulcers can be caused in part by too much acid being made in the stomach.
- TACIDINE is also used to stop duodenal ulcers from coming back.

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

2. What should I know before I take TACIDINE?

Warnings

You should tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions. It is very important that your doctor is aware of these matters when determining whether or not to prescribe TACIDINE.

Do not take TACIDINE if:

- you have ever had an allergic reaction to TACIDINE, any other histamine H2-receptor antagonists (e.g. cimetidine, ranitidine, famotidine) or any of the ingredients listed at the end of this leaflet (see section [7. Product details](#))
Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed. If you take this medicine after the expiry date has passed it may not work as well.

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes
- have or have had any of the following medical conditions:
 - o kidney or liver disease
 - o chronic lung disease
 - o diabetes
 - o a weakened immune system or lowered resistance to infection, sometimes caused by certain diseases or treatments.
- plan to have surgery.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in TACIDINE passes into breast milk and there is a possibility that your baby may be affected.

Use in children

TACIDINE is not recommended for use in children, as the safety and effectiveness has not been established.

3. What if I am taking other medicines?

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

Some medicines may interfere with TACIDINE and affect how it works. These include:

- aspirin
- certain antacids used to treat heartburn and indigestion.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect or are affected by TACIDINE.

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist will be able to tell you what to do when taking TACIDINE with other medicines.

4. How do I take TACIDINE?

Follow all directions given to you by your doctor or 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 for help.

How much to take

Your doctor will tell you how much TACIDINE you need to take each day depending on your condition. The dose varies from person to person.

- duodenal and stomach ulcers - the recommended dosage is 150 mg twice a day 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 to take a lower dose.

How to take TACIDINE

Swallow the capsules whole with a full glass of water.

When to take TACIDINE

- Take your medicine at about the same time each day.
Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- TACIDINE can be taken with or without food.
- The 150 mg capsule is usually taken in the morning and in the evening before you go to bed.
- The 300 mg capsule is usually taken once daily, at bedtime.

How long to take TACIDINE for

Your doctor will tell you how long you should continue taking TACIDINE capsules.

Do not stop taking the capsules just because you feel better. This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well. If you stop taking your capsules too early then your condition will not have been properly treated.

If you forget to take TACIDINE

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 TACIDINE as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much TACIDINE

If you think that you or anyone else has taken too much TACIDINE, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking TACIDINE?

Things you should do

- Tell your doctor or pharmacist if you start any new medicine while you are taking TACIDINE.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- If you are going to have surgery, including dental surgery, tell the surgeon, anaesthetist or dentist that you are taking this medicine.
It may affect other medicines used during surgery.
- If you are taking TACIDINE for an ulcer, you should go to your doctor regularly for check-ups to make sure that TACIDINE has healed your ulcer.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- Keep all of your doctor's appointments so that your progress can be checked.

Things you should not do

- Do not give TACIDINE to anyone else, even if they have the same condition as you. Your doctor has prescribed it for you and your condition.
- Do not take TACIDINE to treat any other complaints unless your doctor tells you to.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking your medicine too soon then your condition may not have been properly treated.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TACIDINE affects you.

TACIDINE may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Make sure you know how you react to TACIDINE before you drive a car or operate any machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Your doctor may advise you to limit your alcohol intake while you are being treated for your condition.

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.

- Aspirin and 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 mealtimes.
- Smoking - your doctor may advise you to stop smoking or at least cut down.

Looking after your medicine

- Keep the capsules in their blister pack until it is time to take them.
If you take the capsules out of the blister pack they may not keep well.
- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat or dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Don't be alarmed by the following list of side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• sweating • itchy skin rash or hives • headaches • flatulence, vomiting, diarrhoea, constipation	Speak to your doctor if you have any of these less serious side effects and they worry you. These are the more common side effects of TACIDINE. They are usually mild and short-lived.

Serious side effects

Serious side effects	What to do
• yellowing of the whites of the eyes or skin, also called jaundice • dark urine • symptoms of anaemia, which may include tiredness, dizziness and looking pale • confusion	Call your doctor straight away if you notice any of these serious side effects.

Very serious side effects

Very serious side effects	What to do
• vomiting blood or food	Call your doctor straight

Very serious side effects	What to do
- 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, tongue or back of throat which may cause difficulty in swallowing or breathing; wheezing or shortness of breath - chest pain	away or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.

Incidences of abnormal liver function accompanied by jaundice (yellow skin) have been rarely reported by patients taking this medicine. This side effect has been reversed when TACIDINE is stopped.

Prolonged use of TACIDINE may impair the absorption of Vitamin B12.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What TACIDINE contains

Active ingredient (main ingredient)	nizatidine 150 mg or 300 mg
Other ingredients (inactive ingredients)	- colloidal anhydrous silica - croscarmellose sodium - pregelatinised maize starch - purified talc - sodium lauryl sulfate - magnesium stearate - quinoline yellow (150 mg only) - allura red AC (150 mg only) - iron oxide red (300 mg only) - iron oxide yellow - titanium dioxide - gelatin

	- TekPrint SW-9008 Black Ink (ID 2328) - TekPrint SW-9009 Black Ink (ID 2343)
Potential allergens	phenylalanine

Do not take this medicine if you are allergic to any of these ingredients.

What TACIDINE looks like

TACIDINE 150 mg is a hard gelatin capsule with a pale yellow body and dark yellow cap. The body has "NZ 150" and the cap has "G" printed in black. (AUST R 94204).

TACIDINE 300 mg is a hard gelatin capsule with a light brown body and cap. The body has "NZ 300" and the cap has "G" printed in black. (AUST R 94205).

TACIDINE 150 mg is available in blister packs of 60 capsules.

TACIDINE 300 mg is available in blister packs of 30 capsules.

Who distributes TACIDINE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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TACIDINE® is a Viatris company trade mark

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