

TAGAMET

Cimetidine

Consumer Medicine Information Leaflet

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about TAGAMET. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the possible risks of taking TAGAMET against the expected benefits.

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

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

WHAT TAGAMET IS USED FOR

TAGAMET contains cimetidine as the active ingredient.

TAGAMET helps heal peptic ulcers and relieves the pain and discomfort they cause. Peptic ulcers can also be called gastric ulcers or duodenal ulcers depending on where they occur. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out of the stomach. These can be caused in part by the acid made in the stomach.

TAGAMET is also used to treat reflux oesophagitis or reflux disease. This can be caused when food and acid from the stomach washes back into the food pipe (oesophagus).

This can cause a burning feeling in the chest known as heartburn. Heartburn usually occurs after eating or at night. TAGAMET relieves these symptoms and helps heal any damage to the food pipe.

TAGAMET is also used to treat a rare condition called Zollinger-Ellison syndrome. In this condition the stomach produces very large amounts of acid.

TAGAMET belongs to a class of medicines called H2 antagonists or H2 blockers. It works by reducing the amount of acid produced by your stomach. This helps to reduce pain and allows any damage to heal.

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

There is no evidence that TAGAMET is addictive.

BEFORE TAKING TAGAMET

DO NOT TAKE TAGAMET IF:

- * you have had an allergic reaction to cimetidine or any of the other ingredients contained in this medicine. The ingredients are listed at the end of this leaflet. Cimetidine is also contained in *Magicul*. Signs of an allergic reaction may include an itchy skin rash, shortness of breath and swelling of the face or tongue.

If you have taken cimetidine

before and became unwell, tell your doctor or pharmacist before taking the first dose.

- * the expiry date printed on the pack has passed.
- * the packaging is torn or shows signs of tampering.

TAGAMET should not be given to children unless instructed to by your doctor. There is only a small amount of information available about the use of TAGAMET in children.

Do not give this medicine to anyone else; your doctor has prescribed it specifically for you and your condition.

BEFORE YOU START TAKING TAGAMET TELL YOUR DOCTOR IF:

- * you are or think you may be pregnant or if you intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of using TAGAMET during pregnancy.
- * you are breast feeding. Your baby can absorb cimetidine from breast milk if you are breast feeding.
- * you have any kidney or liver problems. The dose of TAGAMET may need to be adjusted if you have kidney problems.
- * you are on a low salt diet. Effervescent TAGAMET tablets contain sodium (salt).
- * you have phenylketonuria. Effervescent TAGAMET tablets contain aspartame.

TAKING OTHER MEDICINES WITH TAGAMET:

Do not take Tagamet with the heart medication dofetilide.

TAGAMET may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when taking TAGAMET with other medicines.

It is very important to tell your doctor if you are taking any other medicines, if you have taken other medicines until recently, or if you start new ones - these include other medicines or supplements you have been given or those medicines that you buy without a prescription. In particular mention if you are taking medicines which:

- * lower blood pressure or treat heart conditions (e.g. nifedipine)
- * control epilepsy (eg. phenytoin)
- * thin blood (eg. warfarin)
- * treat breathing problems (eg. theophylline)
- * relieve arthritis or other pain
- * treat depression or anxiety
- * contain chlormethiazole or metformin

Antacids should be taken at least 1 hour before or after taking cimetidine. Some antacids may reduce the absorption of cimetidine.

HOW TO TAKE TAGAMET

Follow your doctors' instructions about how and when to use TAGAMET. Read the direction label carefully. If you have any concerns about how to take this medicine talk to your doctor or pharmacist.

HOW MUCH TO TAKE

To treat an ulcer the usual dose of TAGAMET is 800 mg each day. This can be taken once daily at bed-time or as 400 mg in the morning and 400 mg at bed-time.

To prevent an ulcer from forming again the usual dose is 400 mg at bed-time.

In reflux disease, the usual adult dose is 800 mg each day. This can be taken once daily at bed-time or as 400 mg in the morning and 400 mg at bed-time.

For short term relief of heartburn or other symptoms of reflux disease the dose is 200mg up to four times per day. A second tablet should not be taken for at least one hour. TAGAMET does not provide instant relief of symptoms.

For other conditions the dose prescribed by your doctor may be different.

HOW TO TAKE IT

Take the green TAGAMET tablets with a full glass of water or another liquid. The 800 mg tablets can be broken in half (along the break-line). Do not chew the tablets.

Dissolve the large white effervescent TAGAMET tablets in half a glass of water before swallowing. The tablet will dissolve completely.

TAGAMET can be taken with or without food. Food does not alter the effects of TAGAMET.

Take TAGAMET at the same time each day. Taking your medicine at the same time each day will give the best effect. It will also help you to remember when to take your medicine.

If you are having haemodialysis, the tablets should be taken after dialysis.

HOW LONG TO TAKE IT

If you are taking TAGAMET for relief of heartburn and other symptoms of reflux disease you should not continue treatment longer than 2 weeks. If your symptoms have not improved with TAGAMET or continue you should see your doctor.

If you are taking TAGAMET to heal an ulcer you will need to take it for 4

to 8 weeks.

If you are taking TAGAMET to treat reflux disease you may need to take it for up to 12 weeks.

If you are taking TAGAMET to stop an ulcer coming back or for Zollinger-Ellison syndrome, your doctor will let you know how long you need to take the tablets. Your doctor will need to assess your condition regularly.

Keep taking TAGAMET for as long as your doctor tells you to. Do not stop taking TAGAMET just because you feel better.

IF YOU FORGET TO TAKE IT

If it is almost time for your next dose, leave out the dose you missed and take your next dose when you are meant to. Otherwise, take the dose as soon as you remember, and then go back to taking it as you normally would.

Do not try to make up for missed doses by taking more than one dose at a time.

Taking more than the prescribed dose can increase the chance of unwanted side effects.

OVERDOSE

Immediately telephone your doctor or Poisons Information Centre or go to the emergency department at your nearest hospital if you or anyone else has taken a large amount of TAGAMET. Do this even if there are no signs of discomfort or poisoning.

WHILE YOU ARE USING TAGAMET

THINGS YOU MUST DO:

Take TAGAMET exactly as your doctor has prescribed.

Tell your doctor or pharmacist you are taking TAGAMET, before

starting any other medicines. Some medicines may affect the way other medicines work.

Tell your doctor if you become pregnant while taking TAGAMET.

Tell your doctor immediately if you develop any of the following. These may be complications of your condition:

- * ongoing stomach pains
- * unexpected weight loss
- * passing black motions
- * vomiting blood

THINGS TO BE CAREFUL OF:

Be careful driving or operating machinery until you know how TAGAMET affects you. TAGAMET may cause dizziness or drowsiness in some people. Make sure you know how you react to TAGAMET before you drive a car or operate machinery.

OTHER THINGS YOU CAN DO TO HELP:

Avoid or reduce drinking alcohol. Drinking alcohol may worsen your symptoms.

Avoid or reduce smoking. Smoking can affect ulcer healing.

Change your eating habits. Eat smaller meals and eat slowly. Avoid food that causes you stomach pain and discomfort.

Talk to your doctor or pharmacist about other measures that may help you.

SIDE EFFECTS

Besides their main effect, medicines may have some unwanted effects. Unwanted effects do not always occur in every person.

Most unwanted effects following TAGAMET are mild, and may disappear without stopping TAGAMET. However, some side effects may need medical treatment.

Tell the doctor about any effect which is troublesome or ongoing.

MILD EFFECTS

- * **Tell your doctor if you notice any of the following that are troublesome or ongoing:**
 - headache, tiredness, dizziness or drowsiness
 - vomiting or feeling sick, flatulence (wind), diarrhoea or constipation
 - mild skin rash, muscle aches and pains, hair loss
 - in men: enlarged breasts and sexual problems (these have been reported rarely)

MORE SERIOUS EFFECTS

- * **Tell your doctor immediately if you notice any of the following:**
 - depressed mood or confusion
 - fast heart beat, slow heart beat or irregular heart beat
 - unusual bleeding or bruising
 - yellowing of the skin and eyes also called jaundice
 - fever
- * **Stop taking TAGAMET and contact a doctor immediately or go to the emergency department of your nearest hospital if any of the following happens:**
 - swelling of limbs, face, mouth or throat
 - shortness of breath or breathing difficulties
 - hives or severe skin reactions

These reactions are signs of a severe allergic reaction to TAGAMET.

Allergy to TAGAMET is rare.

- * **Other rare events that have been reported with TAGAMET include:**
 - inflammation of the liver, pancreas or kidney
 - blood disorders

You should tell your doctor or pharmacist as soon as possible if any of these, or any other unusual events or problems occur during or

after treatment with TAGAMET.

STORAGE

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

Keep the pack in a cool dry place where it stays below 30 degrees C.

Do not leave it in the car on a hot day. Do not store medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Keep all medicines out of the reach of children, such as in a locked cupboard.

If your doctor tells you to stop taking TAGAMET ask your pharmacist what to do with any tablets that are left over.

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE

TAGAMET comes as:

- * a round, pale green tablet containing 200 mg of cimetidine. The tablet is marked SKF 200 on one side.
- * a capsule-shaped, pale green tablet containing 400 mg of cimetidine. The tablet is marked TAGAMET on one side and SK&F 400 on the other side.

OTHER INGREDIENTS:

The tablets contain the colouring agents: titanium dioxide CI 77891, indigo carmine CI 73015, iron oxide black CI 77499 and iron oxide yellow CI 77492.

They also contain: cellulose-microcrystalline, starch-maize, povidone, sodium lauryl sulfate, magnesium stearate, sodium starch glycollate and

carnauba wax.

CI = Colour Index (Society of Dyers and Colourists)

TAGAMET tablets do not contain sucrose, lactose, gluten, or tartrazine.

FURTHER INFORMATION

TAGAMET tablets come in the following packs: 200 mg in packs of 120 (AUST R 13016) and 400 mg in packs of 60 (AUST R 13017).

SPONSOR

GlaxoSmithKline Australia Pty Ltd
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Tagamet is a registered trade mark of the GlaxoSmithKline Group of Companies.

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