Package Leaflet: Information for the user

Tagamet® Syrup 200 mg/5 ml
cimetidine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tagamet® Syrup 200 mg/5 ml is and what it is used for

Tagamet Syrup contains cimetidine which is a histamine H_2 antagonist. It helps to reduce the natural production of acid in the stomach.

It is used to treat and relieve:
- the symptoms of peptic ulcers which occur in the stomach or intestine (gut)
- oesophageal reflux disease which 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
- a rare condition called Zollinger-Ellison syndrome when the stomach produces very large amounts of acid.

This medicine may also be prescribed for a range of other medical conditions where a reduction of acid production in the stomach is needed, or to protect your stomach from other medicines (such as non-steroidal anti-inflammatories).

2. What you need to know before you take Tagamet® Syrup 200 mg/5 ml

Do not take Tagamet Syrup:
- if you are allergic to cimetidine or to any of the other ingredients of this medicine (listed in section 6).

If this applies to you, speak to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tagamet Syrup:
- if you have a kidney problem
- if you have a blood disease
- if you have had a peptic ulcer and are also taking a non-steroidal anti-inflammatory drug (NSAID), (e.g. ibuprofen)
- if you are pregnant or planning a pregnancy
- if you are breast-feeding.

Other medicines and Tagamet Syrup

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may be affected by Tagamet or they may affect how well Tagamet will work. Tell your doctor or pharmacist if you are taking medicines which:
- control epilepsy (e.g. phenytoin). Your doctor will monitor you
- thin the blood (e.g. warfarin). Your doctor will monitor you
- treat breathing problems (e.g. theophylline)
- may cause your blood cell count to change (e.g. antibiotics)
- treat fungal (yeast) infections (e.g. ketoconazole, itraconazole, posaconazole)
- treat diabetes (e.g. glipizide, metformin)
- treat anxiety (e.g. diazepam)
- treat depression, called tricyclic antidepressants (e.g. amitriptylline)
- lower blood pressure or treat heart conditions (e.g. metoprolol, propranolol, nifedipine, diltiazem, procainamide)
- numb the body such as anaesthetics used in hospital (e.g. lidocaine)
- are strong pain relievers (e.g. morphine)
- suppress the immune system (e.g. ciclosporin, tacrolimus)
- treat HIV/AIDS (e.g. atazanavir)
- treat tumours or cancer (e.g. carmustine, fluorouracil, epirubicin), or if you are having radiation therapy.

Pregnancy and breast-feeding

Do not take Tagamet if you are pregnant, planning to become pregnant or breast-feeding unless advised to by your doctor.

Driving and using machines

Tagamet syrup is unlikely to affect your ability to use machinery or to drive.

Tagamet Syrup contains:
- **Sodium**

  This medicine contains 2.56 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.13% of the recommended maximum daily dietary intake of sodium for an adult.
- **Methyl hydroxybenzoate and propyl hydroxybenzoate**

  These may cause allergic reactions (possibly delayed).
- **Sucrose**

  If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.
- **Sorbitol**

  This medicine contains 350 mg sorbitol in each 5 ml spoonful which is equivalent to 70 mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

  Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- **Sunset yellow**

  This may cause allergic reactions.
- **Ethanol (alcohol)**

  This medicinal product contains 3 vol % ethanol (alcohol), i.e. up to 1.42 g per maximum daily dose (60 ml), equivalent to 36 ml beer, 15 ml wine per 60 ml. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.
- **Propylene glycol**

  This medicine contains 500 mg propylene glycol in each 5 ml which is equivalent to 100 mg/ml.

  If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

  If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

  If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

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3. How to take Tagamet® Syrup 200 mg/5 ml

Always take this medicine exactly as your doctor has told you. Your doctor will decide on the appropriate dose to suit your condition. Check with your doctor or pharmacist if you are not sure.

- Take the syrup with meals or at bedtime as advised by your doctor.

The recommended dose is:

Adults and the elderly: the usual dose is 10 ml twice a day, with breakfast and at bedtime.

Your doctor will tell you the correct dose depending on your condition.

The maximum dose is 60 ml a day.

Use in children and adolescents: your doctor will decide on the dose according to your child's body weight.

The usual length of treatment is at least four weeks though this may be longer in some conditions. Your doctor will advise you.

If you take more Tagamet Syrup than you should

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the bottle and any remaining solution with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Tagamet Syrup

If you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Tagamet Syrup

If you stop your treatment too soon, your symptoms may come back.

You may feel better after a few days, but you should keep taking your medicine until the prescribed course is finished.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP taking the syrup and **seek medical help immediately** if you have any of the following **allergic reactions**:

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps.

Seek immediate medical attention if you have any of the following symptoms:

- unusual bleeding or bruising; or fever, sore throat, mouth ulcers, repeated infections or infections that will not go away. This may be due to changes in your blood
- red spots on the skin which may be painful to touch, joint pain, swollen lymph glands
- yellowing of your skin or eyes, pale faeces and dark urine, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness. This may be due to liver changes
- confusion, hallucinations, depression
- in men: enlarged breasts, trouble getting or keeping an erection
- unexpected secretion of breast milk in men or women
- pain behind the ribs radiating towards the back, often worse when lying down, nausea, vomiting, fever. This may be due to inflammation of the pancreas
- unusually slow or fast heartbeat, irregular heartbeat and fainting
- fever, rash, nausea, aches and pains, change in colour of urine, passing more or less urine than usual or passing urine at night. These problems may indicate kidney changes
- aching or weak muscles, or aching joints.

Other possible side-effects:

Common (affects 1 to 10 users in 100)

- diarrhoea
- dizziness
- tiredness
- mild skin rash
- headache.

Very rare (affects less than 1 user in 10,000)

- hair loss.

Side effects with Tagamet Syrup are usually mild and do not last long.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tagamet® Syrup 200 mg/5 ml

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle label and on the carton after EXP. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tagamet Syrup contains

- The active substance is cimetidine. Each 5 ml spoonful of Syrup contains 200 mg cimetidine.
- The other ingredients are:
  saccharin sodium, hydrochloric acid, ethanol (alcohol), methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), propylene glycol, sodium chloride, disodium hydrogen phosphate, sorbitol (E420), sucrose, sunset yellow (E110), peach flavour, Mafco Magnasweet 180, ethylene oxide and propylene oxide polymer and water.

  (See end of Section 2 for further information on sodium, ethanol, sorbitol, sucrose, sunset yellow, methyl hydroxybenzoate, propyl hydroxybenzoate and propylene glycol).

What Tagamet Syrup looks like and contents of the pack

Tagamet Syrup is a clear, orange-coloured syrup with a peach-flavour.

It is available in bottles of 600 ml.

Marketing Authorisation Holder

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Manufacturer

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