

AXCEL CIMETIDINE TABLET

Cimetidine (200mg, 400mg)

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What Axcel Cimetidine Tablet is used for

Axcel Cimetidine Tablet is used for the following treatment:

- Active ulcers in the stomach and intestine and recurrent ulceration.
- Persistent indigestion symptoms.
- Nonsteroidal anti-inflammatory drug (NSAIDs) - induced lesions (ulcers, erosions) and symptoms.
- Gastro-esophageal reflux disease (content of the stomach comes up into the esophagus (food pipe)).
- Zollinger-Ellison syndrome and other cases of high gastric secretion.
- To be used with enzyme supplements in people with pancreatic problems.

How Axcel Cimetidine Tablet works

Cimetidine belongs to a group of medicines called H₂-receptor antagonists. Cimetidine inhibits both the secretion of gastric acid and reduces pepsin enzyme output. It also has a beneficial effect in maintaining the integrity of the gastric lining barrier.

Before you use Axcel Cimetidine Tablet

– When you must not use it

Do not take Axcel Cimetidine Tablet if:

- You are allergic or hypersensitive to Cimetidine or other ingredients.
- You are pregnant or nursing mother unless essential.

– Before you start to use it

Tell your doctor if:

- You have a history of digestive ulcer, particularly the elderly.
- You have severely impaired kidney function.
- You have medication treatment or with illness that could cause falls in blood cell count.

Cimetidine treatment can mask the symptoms and allow transient healing of gastric cancer. Your doctor may plan some tests to exclude gastric cancer.

– Taking other medicines

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Cimetidine Tablet:

- Warfarin-type anticoagulant (used to treat blood clots).
- Phenytoin (used to treat seizures).
- Propranolol (used to treat high blood pressure and other heart conditions).
- Nifedipine (used to treat high blood pressure).
- Chlordizepoxide, diazepam (used to treat anxiety and acute alcohol withdrawal).
- Certain tricyclic antidepressants.
- Lidocaine (used to reduce pain or discomfort).
- Theophylline (used to treat lung disease).
- Metronidazole (antibiotic).

How to use Axcel Cimetidine Tablet

– How much to use

For oral use only.

Active ulcer:

800mg as a single dose at bedtime or 400mg twice daily with breakfast and at bedtime. Treatment should be continued for at least 4 weeks, even

if symptomatic relief has been achieved in shorter time.

Prevention of recurrent ulcer:

Maintenance dose of 400mg at bedtime for as long as the physician deems necessary to prevent a relapse.

Persistent indigestion symptoms:

200mg twice daily after breakfast and at bedtime. Individual courses of treatment should not exceed 4 weeks.

Treatment of NSAID- induced lesion (ulcers, erosions) and symptoms:

800mg daily, either as 800mg at bedtime or 400mg twice daily at breakfast and at bedtime. Treatment should be given for at least 4 weeks. Maintenance treatment is 400mg at bedtime.

Gastro-esophageal reflux disease:

0.8 – 1.6g/day, depending on the degree of severity of the condition. A single bedtime dose of 800mg or 400mg twice daily in the morning and a bedtime. Treatment should be taken for up to 12 weeks. 200mg 4 times daily with meals and at bedtime has been show effective in heartburn.

In Zollinger-Ellison Syndrome and other cases of high gastric secretion:

Doses should be adjusted to individual needs and should continue as long as clinically indicated. Doses up to 12g/day have been used.

In pancreatic insufficiency as an adjunct to enzyme supplement therapy:

0.8 – 1.6g/ day, depending upon individual response, in 4 divided doses, one to one and half hours before meals.

Dosage should be reduced in people with impaired kidney function according to creatinine clearance.

Elderly

The normal adult dosage may be used unless kidney function is markedly impaired.

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Children

In children more than one year old, 25-30 mg/kg body weight per day in divided doses.

– When to use it

Your doctor will decide when it is appropriate for you to take Axcel Cimetidine Tablet according to the type of condition you have.

– How long to use it

- Take this medicine as stated in the leaflet without exceeding the dosage.
- Follow any recommendations and advices from your doctor or pharmacist.

– If you forget to use it

- Do not double up the dosage as Axcel Cimetidine Tablet may give you unacceptable side effects.

– If you use too much (overdose)

- It is advisable for you to contact your doctor immediately or go to the Emergency Department of your nearest hospital if you did take Axcel Cimetidine Tablet too much.

While you are using it

– Things you must do

- Discuss with your doctor or pharmacist the dos' and don'ts' while taking this medicine.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

– Things you must not do

- Do not take your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during any single consumption.

– Things to be careful of

- Care should be taken to observe periodically if given prolonged treatment.

Side effects

Like all medicines, Axcel Cimetidine Tablet can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following side effects have been reported:

Headache, muscle pain, joint pain, slow heart rate, a faster than normal heart rate, heart block (abnormal heart rhythm) and reversible inability to achieve or maintain an erection. Diarrhoea, tiredness, dizziness, rash in small number of people. Enlargement of a man's breasts, rarely. Decrease white blood cell counts mostly in people also receiving medicine known to reduce blood counts.

Very rare cases of low blood platelet count and aplastic anaemia (deficiency of all types of blood cells). A few cases of reversible confusion, mostly in elderly and/or severely ill person. Rare case of inflammation of the liver, pancreas and kidney.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website np.ra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and disposal of Axcel Cimetidine Tablet

– Storage

Keep Axcel Cimetidine Tablet out of reach of children.

Store below 30°C. Keep container well closed and protect from light.

– Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

– What it looks like

Axcel Cimetidine-200 Tablet
Light green, biconvex, round, film-coated tablet, 9.8 mm in diameter with a single score-line on one side and marked KOTRA logo on the other side.

Axcel Cimetidine-400 Tablet

Light green, elongated tablets, 18.8mm in length.

– Ingredients

-Active Ingredient (s):
Cimetidine

-Inactive Ingredients:

Lactose, Microcrystalline Cellulose, Sodium Lauryl Sulphate, Aerosil 200, PVP K30, Quinoline Yellow, Brilliant Blue Dye, Magnesium Stearate, Corn Starch, Sodium Starch Glycollate, Purified Water and Film Coating agents (Opadry White, Quinoline Yellow and Brilliant Blue).

– MAL Number

Axcel Cimetidine-200 Tablet
MAL07101253AZ

Axcel Cimetidine-400 Tablet

MAL19940271AZ

Manufacturer and product registration holder

Kotra Pharma (M) Sdn Bhd
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