AXCEL EVILINE TABLET

Magnesium Hydroxide/ Aluminium Hydroxide/ Simethicone (200mg/ 200mg/ 20mg)

What is in this leaflet

- 1. What Axcel Eviline Tablet is used for
- 2. How Axcel Eviline Tablet works
- 3. Before you use Axcel Eviline
- 4. How to use Axcel Eviline Tablet
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of Axcel Eviline Tablet
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

What Axcel Eviline Tablet is used for

Axcel Eviline Tablet is an antacid / deflatulent for symptomatic treatment of:

- Stomach ulcer.
- Indigestion of functional or organic origin.
- Heartburn in hiatus hernia or pregnancy.
- Flatulence and abdominal distension.
- Gastritis oesophagitis (inflammation of the esophagus lining).
- Other conditions where hyperacidity or flatulence may be present

How Axcel Eviline Tablet work

Axcel Eviline Tablet is an antacid used to prevent and relief pain in the symptomatic management of gastric and duodenal ulcers and gastrointestinal reflux by neutralising hydrochloric acid in the gastric secretions.

Before you use Axcel Eviline Tablet

- When you must not use it

- Hypersensitivity to active substance or any of the excipients. Signs of an allergic reaction are skin rash, swelling of the lips, tongue, face and throat; and breathing problems.
- Porphyria
- Serious kidney problems
- Children
- Cachexia

- Before you start to use it

- Axcel Eviline Tablet is not recommended for children.
- Inform your doctor if you have kidney disease.

Pregnancy

 Axcel Eviline Tablet should only be used when absolutely necessary. Consult your doctor to make an evaluation of the expected benefit for the mother in relation to the risk for the fetus or baby.

Lactation

 Axcel Eviline Tablet is considered compatible with breast-feeding.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Some drugs may be affected by magnesium hydroxide or may affect how it works.

This medicine can interfere with the effects of:

- Medicines used to control stomach acidity (H₂ antagonists);
- Medicines for the heart and blood pressure (atenolol, digoxin, metoprolol and propranolol);
- Anti-infective (cefdinir, tetracyclines, fluoroquinolones, lincosamides, ketoconazole);
 Mnti-infective medicines cefpodoxime, tetracyclines, ethambutol, isoniazid, penicillamine, medicines
- Antimalarial medicines (chloroquine);
- Anti-inflammatory medicines (diflunisal, glucocorticoids, indomethacin);
- Medicines for bone diseases (bisphosphonates);
- Medicines for the thyroid (levothyroxine);

- Medicines against schizophrenia (phenothiazine neuroleptics);
- Medicines to lower cholesterol (rosuvastatin);
- Medicines containing iron or sodium fluoride.

Wait at least two hours (4 hours for fluoroquinolones), before taking Axcel Eviline Tablet to avoid interaction with the other medicines.

You must also tell your doctor or pharmacist if you are taking:

- Medicines containing polystyrene sulfonate (Kayexalate), due to the risk of metabolic and intestinal problems.
- Medicines containing aluminium hydroxide and citrates, due to the risk of increased aluminium in the blood.
- Quinidine (medicine for the heart) due to the risk of increased quinidine levels.
- Salicylates.

How to use Axcel Eviline Tablet

- How much to use

Two to four tablets, well chewed, four times a day. Do not take more than 16 tablets in a 24-hour period.

- When to use it

Take twenty minutes to one hour after meals and at bedtime, or as directed by your doctor.

- How long to use it

Continue taking Axcel Eviline Tablet for as long as doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

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- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take high doses of this medicine, the following may occur:

- Diarrhea, abdominal pain and vomiting
- Worsening of intestinal problems if you have constipation, have non-serious kidney problems or are elderly.

While you are using it

- Things you must do
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Axcel Eviline Tablets.
- Tell your doctor immediately if you become pregnant while talking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Axcel Eviline Tablets to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Tell your doctor immediately if you become pregnant while taking this medication.

Talk to your doctor or pharmacist before taking Axcel Eviline Tablet.

- If you have intestinal problems or constipation, if you have non-serious kidney problems, or if you are elderly, as this medicine may worsen intestinal problems,
- If you are following a low phosphorus diet, if you have low levels of phosphates in the blood (hypophosphatemia) or if

you are receiving long-term treatment. This medicine reduces phosphate levels in the blood and can cause bone problems.

 If you are taking high doses of this medicine or if you are subject to diarrhea, pay careful attention because this medicine can cause diarrhea.

Side effects

Like all medicines, Axcel Eviline Tablets 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:

Uncommon side effects

• Diarrhea and constipation

Very rare side effects

• Hypermagnesemia

Not known frequency side effects:

- Excessive reaction of the body to foreign substances (hypersensitivity reactions, including serious ones), a skin rash that may be itchy, characterized by swelling of the skin (hives), itching.
- Changes in aluminium and phosphate levels in the blood, which can cause bone problems.
- Abdominal pain.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Axcel Eviline Tablet

- Storage

Keep Axcel Eviline Tablet out of reach of children.

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

- <u>Disposal</u>

Do not use Axcel Eviline Tablets after the expiry date which is stated on the carton.

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 Eviline Tabletss is a white, flat, round tablets, 12.9mm in diameter, and marked KOTRA logo on one side.

- Ingredients

- Active Ingredients:
 Magnesium Hydroxide,
 Aluminium Hydroxide and Simethicone.
- Inactive Ingredients:
 PVP K90, Corn Starch,
 Magnesium Stearate, Purified
 water, Saccharin Sodium,
 Peppermint Oil, Lactose, Icing
 Sugar, and Mannitol.

- <u>MAL Number</u> MAL19911458X

Manufacturer and Product Registration Holder

Kotra Pharma (M) Sdn Bhd No. 1, 2 & 3, Jalan TTC 12, Cheng Industrial Estate, 75250 Melaka, Malaysia.

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