

INFORMATION FOR THE PATIENT

APO-OMEPRAZOLE

Omeprazole Capsules

Read this leaflet carefully. It contains general points about APO-OMEPRAZOLE and should add to more specific advice from your doctor or pharmacist.

WHAT IS APO-OMEPRAZOLE USED FOR AND HOW DOES IT WORK?

APO-OMEPRAZOLE is the brand name for a drug called omeprazole.

The most common uses of APO-OMEPRAZOLE are:

- for stomach ulcers or for duodenal ulcers,
- for ulcers caused by your medicine for pain and joint problems (NSAID-associated gastric and duodenal ulcers), and
- for the symptoms of gastroesophageal reflux disease such as: a burning sensation rising from the chest towards the neck (heartburn) and flow of bitter/sour juice into the mouth (regurgitation).

APO-OMEPRAZOLE may also be used in rare conditions like "Zollinger-Ellison syndrome", where the stomach produces large amounts of acid. APO-OMEPRAZOLE works by reducing the amount of acid made in your stomach. This helps in treating acid-related and bacteria-related stomach problems.

Your doctor will have explained why you are being treated with APO-OMEPRAZOLE and will have told you what dose to take. Follow those directions carefully. They may differ from the information contained in this leaflet.

WHAT IS IN APO-OMEPRAZOLE?

Each APO-OMEPRAZOLE capsule contains omeprazole as the active ingredient. In addition, it contains the following non-medicinal ingredients (listed in alphabetical order): eudragit, gelatin, magnesium hydroxide, mannitol, povidone, red iron oxide, titanium dioxide and triethyl citrate.

Check with your doctor or pharmacist if you think you might be allergic to any of the "non-medicinal" substances which may be present in APO-OMEPRAZOLE.

WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING APO-OMEPRAZOLE?

Tell your doctor:

- about all health problems you have now or have had in the past,
- about other medicines you take, including ones you can buy without a prescription,
- if you are allergic to "non-medicinal" substances which may be present in APO-OMEPRAZOLE, and
- if you are pregnant, plan to become pregnant or are breastfeeding.

HOW DO I TAKE APO-OMEPRAZOLE PROPERLY?

Take all doses of APO-OMEPRAZOLE, as recommended by your doctor, even when you feel well. Daily doses are needed to help damaged areas heal. The recommended dose for treating acute disease is 20 to 40 mg once a day for 2 to 8 weeks. Your doctor may recommend that you continue taking APO-OMEPRAZOLE 20 to 40 mg to control symptoms of reflux disease, or APO-OMEPRAZOLE 20 mg to prevent ulcers from returning while you continue to take your medicine for pain and joint problems.

Take APO-OMEPRAZOLE until your doctor tells you to stop. Even if you start to feel better in a few days, your symptoms may return if APO-OMEPRAZOLE is stopped too soon. APO-OMEPRAZOLE needs to be taken for the full duration of treatment to help correct acid problems.

If you miss a dose of APO-OMEPRAZOLE and remember within 12 hours, take it as soon as possible. Then go back to your regular schedule. However, if more than 12 hours have passed when you remember, do not take the missed tablet. Just take your next dose on time.

APO-OMEPRAZOLE may be taken with food or on an empty stomach.

ARE THERE ANY SIDE EFFECTS?

Like any medication, APO-OMEPRAZOLE may cause side effects in some people. Side effects that do occur are usually mild and go away a short time after starting APO-OMEPRAZOLE. Tell your doctor if any of the following are severe or bother you for more than one or two days: nausea, stomach upset, diarrhea, constipation, headache or skin rash.

Other unwanted effects which cannot be predicted may occur in rare cases. If you experience any bothersome or unusual effects while using APO-OMEPRAZOLE, check with your doctor or pharmacist.

WHAT SHOULD I DO IN CASE OF OVERDOSE?

Call your doctor or pharmacist right away in case of an overdose. However, no severe symptoms have been seen in patients who have taken doses up to 400 mg.

WHERE SHOULD I KEEP APO-OMEPRAZOLE?

Remember to keep APO-OMEPRAZOLE well out of reach of children. APO-OMEPRAZOLE should be stored at room temperature (15 to 30°C), in tightly closed and moisture resistant containers. Do not keep APO-OMEPRAZOLE in the bathroom medicine cabinet or other warm, moist places.

Keep all capsules in their container until it is time for a dose. If you do not, moisture from the container may damage the capsules.

Do not use Apo-Omeprazole after the expiry date marked on the pack.

IMPORTANT NOTE

This leaflet alerts you to some of the times you should call your doctor. Other situations which cannot be predicted may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using APO-OMEPRAZOLE.

WHO MANUFACTURES APO-OMEPRAZOLE

Apotex Inc.
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REMINDERS:

This medicine has been prescribed only for you. Do not give it to anybody else.

If you require any further information or advise please consult your doctor or pharmacist.

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