PATIENT INFORMATION LEAFLET

PSandoz® Azithromycin

Azithromycin Monohydrate Hemiethanolate
250 mg and 500 mg tablets

SANDOZ

Antibiotic

This summary contains important information about Sandoz Azithromycin. It is not meant to take the place of your doctor's instructions. Read this information carefully before you take Sandoz Azithromycin. Keep this leaflet. You may need to read it again. This leaflet does not contain the complete information about Sandoz Azithromycin. Ask your doctor, nurse or pharmacist if you do not understand any of this information or if you want to know more about Sandoz Azithromycin. This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

WHAT IS SANDOZ AZITHROMYCIN?

Sandoz Azithromycin is an antibiotic medicine taken once a day to treat the following types of infections in adults: bronchitis, certain types of skin infections, strep throat (pharyngitis, tonsillitis), and pneumonia.

Sandoz Azithromycin helps stop the growth of the bacteria that cause infection. It gets into infected tissue where it is released slowly over time. The medicine fights the infection for several days after the last dose is taken.

Can Antibiotics Cure A Cold Or Flu?

No. Antibiotics work only on infections caused by bacteria. They do not kill viruses. No antibiotic, including Sandoz Azithromycin, can treat viral infections such as the common cold and the flu.

What To Tell Your Doctor Before You Start Taking Sandoz Azithromycin?

Only your doctor can decide if Sandoz Azithromycin is right for you. Before you start taking Sandoz Azithromycin, be sure to tell your doctor if you:

- are taking any prescription medicines, including theophylline or warfarin
- are taking any over-the-counter medicines you can buy without a prescription, including natural/herbal remedies or antacids
- are pregnant, think you are pregnant, or are breastfeeding
- have ever had any liver or kidney problems
- have any other medical problems
- have ever had an allergic reaction to any medicines, including antibiotics such as erythromycin
- have ever had an allergic reaction to azithromycin or any of the ingredients of Sandoz Azithromycin tablets (see **WHAT DO SANDOZ AZITHROMYCIN TABLETS CONTAIN?**)

SANDOZ AZITHROMYCIN AND OTHER MEDICINES

Some medicines may affect how well Sandoz Azithromycin works. Check with your doctor before starting any new prescription or over-the-counter medicines, including natural/herbal remedies or antacids, while on Sandoz Azithromycin.

HOW AND WHEN TO TAKE SANDOZ AZITHROMYCIN?

- If your doctor prescribes Sandoz Azithromycin **250 mg tablets for 3 days**, for treatment of bronchitis:

  Days 1 through 3: Take two tablets each day.

  Each tablet contains 250 mg of azithromycin. Sandoz Azithromycin 250 mg tablets are available in blister packs. Sandoz Azithromycin 250 mg tablets should not be used in children.

- If your doctor prescribes Sandoz Azithromycin **500 mg tablets for 3 days**, for treatment of bronchitis:

  Days 1 through 3: Take one tablet each day.

  Each tablet contains 500 mg of azithromicyn. Sandoz Azithromycin 500 mg tablets are available in blister packs. Sandoz Azithromicyn 500 mg tablets should not be used in children.

- If your doctor prescribes Sandoz Azithromycin **250 mg tablets for 5 days**, for treatment of respiratory tract infections or certain types of skin infections:

  Day 1: Take 2 tablets once.

  Days 2 through 5: Take 1 tablet daily.

  Each tablet contains 250 mg of azithromycin. Sandoz Azithromycin 250 mg tablets are available in blister packs. Sandoz Azithromycin 250 mg tablets should not be used in children.

- If your doctor prescribes Sandoz Azithromycin **500 mg tablets for 5 days**, for treatment of respiratory tract infections or certain types of skin infections:

  Day 1: Take 1 tablet.

  Days 2 through 5: Take 1/2 tablet daily.

  Each tablet contains 500 mg of azithromycin. Sandoz Azithromycin 500 mg tablets are available in blister packs. Sandoz Azithromycin 500 mg tablets should not be used in children.

Sandoz Azithromycin tablets can be taken with or without food.

You should begin to feel better within the first few days, but be sure to take Sandoz Azithromycin for the full number of days your doctor prescribed. Although Sandoz Azithromycin dosing is short, you should not expect Sandoz Azithromycin to work faster than antibiotics which are dosed up to 10 days. If you stop taking Sandoz Azithromycin too soon, infection could come back. The next infection may be worse and be more difficult to treat. If you are not able to take all the medicine, tell your doctor.

POSSIBLE SIDE EFFECTS

Like all medicines, Sandoz Azithromycin may cause some side effects that are usually mild to moderate and go away after the medicine is stopped. The most common ones are:

- nausea
- diarrhea
- stomach pain
- vomiting

As with other antibiotics, if you develop diarrhea that becomes severe and watery or does not go away, stop taking the medicine and call your doctor. This could be a sign of a serious medical problem.

Allergic reactions to Sandoz Azithromycin are rare, but these reactions can be very serious if not treated right away by a doctor. If you think that you might be having an allergic reaction to Sandoz Azithromycin, stop taking the medicine and call your doctor right away. If you cannot reach your doctor, go to the nearest hospital emergency room. Symptoms of a severe allergic reaction may include trouble breathing; swelling of the face, mouth, and neck; severe skin rash or blisters.

Sandoz Azithromycin may cause other less common side effects besides those listed here. If you have any unexpected side effects while taking Sandoz Azithromycin, contact your doctor, nurse or pharmacist.

WHAT TO DO FOR AN OVERDOSE?

In case of accidental overdose, call your doctor right away or go to the nearest emergency room.

WHAT DO SANDOZ AZITHROMYCIN TABLETS CONTAIN?

Sandoz Azithromycin 250 mg tablets contain azithromycin monohydrate hemiethanolate equivalent to 250 mg azithromycin and the following inactive ingredients: cellulose microcrystalline, maize starch, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, sodium lauryl sulfate, lactose monohydrate, talc, hydroxypropyl methylcellulose, hydroxypropylcellulose, titanium dioxide, polyethylene glycol and D&C Red # 30 aluminum lake.

Sandoz Azithromycin 500 mg tablets contain azithromycin monohydrate hemiethanolate equivalent to 500 mg azithromycin and the following inactive ingredients: cellulose microcrystalline, maize starch, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, sodium lauryl sulfate, lactose monohydrate, hydroxypropyl methycellulose, titanium dioxide and polyethylene glycol.

HOW TO STORE SANDOZ AZITHROMYCIN?

Keep Sandoz Azithromycin and all medicines out of reach of children. Store Sandoz Azithromycin at controlled room temperature (between 15–30°C).

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