READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Pr Sandoz Azithromycin
Azithromycin Tablets

Read this carefully before you start taking Sandoz Azithromycin and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Sandoz Azithromycin.

What is Sandoz Azithromycin used for?
Sandoz Azithromycin is an antibiotic medicine used to treat the following types of mild to moderate infections by certain microorganisms in adults such as bronchitis, certain types of skin infections, strep throat (pharyngitis, tonsillitis), genitourinary infections, and pneumonia.

Antibacterial drugs like Sandoz Azithromycin treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, Sandoz Azithromycin should be taken exactly as directed. Misuse or overuse of Sandoz Azithromycin could lead to the growth of bacteria that will not be killed by Sandoz Azithromycin (resistance). This means that Sandoz Azithromycin may not work for you in the future. Do not share your medicine.

How does Sandoz Azithromycin work?
Sandoz Azithromycin helps stop the growth of the bacteria that cause infection. It gets into infected tissue where it is released slowly over time so the medicine keeps fighting bacteria for many days after the last dose is taken. This is why Sandoz Azithromycin may be taken for as short a time as one day.

What are the ingredients in Sandoz Azithromycin?
Medicinal ingredients: Azithromycin Dihydrate (250 mg); Azithromycin Monohydrate Hemiethanolate (500 mg)
Non-medicinal ingredients: Cellulose microcrystalline, colloidal anhydrous silica, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, maize starch, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate and titanium dioxide.

Sandoz Azithromycin comes in the following dosage forms:
Tablets: 250 mg, 500 mg

Do not use Sandoz Azithromycin if you:
- have a history of liver problems when you have used azithromycin.
- are hypersensitive (allergic) to azithromycin, or any macrolide or ketolide antibiotic (including erythromycin) or any other ingredient of Sandoz Azithromycin (see “What are the ingredients in Sandoz Azithromycin?”).
To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Sandoz Azithromycin. Talk about any health conditions or problems you may have, including if you:

- have a known prolonged heart cycle (interval) (QT prolongation)
- are currently taking medication known to prolong QT interval (prolong your heart cycle) such as antiarrhythmics (drugs to regulate your heartbeat such as class IA: quinidine, procainamide and class III: dofetilide, amiodarone, sotalol); antipsychotic agents; antidepressants; and fluoroquinolones (a class of antibiotics)
- have a history of life-threatening irregular heartbeat
- have constantly low levels of potassium or magnesium in your blood
- have a history for heart problems such as slow heart rate, irregular heart beat or cardiac insufficiency (your heart has a hard time pumping blood to your body)
- are pregnant or think you are pregnant,
- are breast feeding or planning to breastfeed. Azithromycin has been reported to be excreted in human breast milk. It is not known if Sandoz Azithromycin could affect your baby. Discuss with your doctor.
- have ever had any liver or kidney problems
- have a weak immune system
- have ever had an allergic reaction to any medicines, including antibiotics such as erythromycin
- have myasthenia gravis (a chronic autoimmune neuromuscular disease which causes muscle weakness)
- have hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption as this product contains lactose.

Other warnings you should know about:
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’s dosing is short, you should not expect Sandoz Azithromycin to work faster than other antibiotics which are dosed up to 10 days. If you stop taking Sandoz Azithromycin too soon, your 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.

If you develop diarrhea during or after treatment with Sandoz Azithromycin, tell your doctor at once. Do not use any medicine to treat your diarrhea without first checking with your doctor.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Sandoz Azithromycin:
- Warfarin (or other anticoagulant medicine);
- Cyclosporin (used to suppress the immune system to prevent and treat rejection in organ or bone marrow transplants);
- Digoxin (used for treatment of heart problem);
- Nelfinavir (used for treatment of HIV infections);
• Ergotamine and ergot derivatives (used for migraine treatment). Ergotamine and ergot derivatives should not be used with Sandoz Azithromycin.

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 to take Sandoz Azithromycin?**
Always take Sandoz Azithromycin as the doctor has prescribed for you, depending on the specific condition you have.

Sandoz Azithromycin can be taken with or without food.

**Usual adult dose:**
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.

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.

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.
  Day 2 through 5: Take 1 tablet daily.

If your doctor prescribes **Sandoz Azithromycin 250 mg tablets** for 1 day for treatment of genital ulcers or non-gonococcal urethritis and cervicitis:
  Days 1: Take four tablets once.

If your doctor prescribes **Sandoz Azithromycin 250 mg tablets** for 1 day for treatment of gonococcal urethritis and cervicitis:
  Days 1: Take eight tablets once.

**Overdose:**
If you think you have taken too much Sandoz Azithromycin, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**
If you forget to take a dose, call your pharmacist or doctor. Do not double dose.

**What are possible side effects from using Sandoz Azithromycin?**
These are not all the possible side effects you may feel when taking Sandoz Azithromycin. If you experience any side effects not listed here, contact your healthcare professional.
Side effects may include:
- Diarrhea/loose stools
- Stomach pain
- Nausea and vomiting
- Headache

### Serious side effects and what to do about them

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If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.
Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:
· Online at MedEffect (www.healthcanada.gc.ca/medeffect);
· By calling 1-866-234-2345 (toll-free);
· By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to:  Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9
    Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store Sandoz Azithromycin at controlled room temperature (between 15°C-30°C).

Keep out of reach and sight of children.

If you want more information about Sandoz Azithromycin:
  • Talk to your healthcare professional
  • Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer’s website www.sandoz.ca or by calling 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

Last revised:  September 23, 2016
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PR SANDOZ AZITHROMYCIN
Azithromycin for Oral Suspension

Read this carefully before you start taking Sandoz Azithromycin and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Sandoz Azithromycin.

What is Sandoz Azithromycin used for?
Sandoz Azithromycin is an antibiotic medicine used to treat the following types of mild to moderate infections by certain microorganisms in children: ear infections, pneumonia, and throat infections and in adults who have difficulty swallowing tablets, for various conditions.

Antibacterial drugs like Sandoz Azithromycin treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, Sandoz Azithromycin should be taken exactly as directed. Misuse or overuse of Sandoz Azithromycin could lead to the growth of bacteria that will not be killed by Sandoz Azithromycin (resistance). This means that Sandoz Azithromycin may not work for you in the future. Do not share your medicine.

How does Sandoz Azithromycin work?
Sandoz Azithromycin helps stop the growth of the bacteria that cause infection. It gets into infected tissue where it is released slowly over time so the medicine keeps fighting bacteria for many days after the last dose is taken. This is why Sandoz Azithromycin may be taken for as short a time as one day.

What are the ingredients in Sandoz Azithromycin?
Medicinal ingredients: Azithromycin Monohydrate
Non-medicinal ingredients: Aspartame, colloidal anhydrous silica, cream caramel, hydroxypropylcellulose, sucrose, titanium dioxide, trisodium phosphate anhydrous and xanthan gum.

Sandoz Azithromycin comes in the following dosage forms:
Powder for oral suspension – azithromycin 300, 600, 900 or 1500 mg/bottle, or 100 mg/5 ml, 200 mg/5 ml when reconstituted (as azithromycin monohydrate).

Do not use Sandoz Azithromycin if you:
• have a history of liver problems when you have used azithromycin.
• are hypersensitive (allergic) to azithromycin, or any macrolide or ketolide antibiotic (including erythromycin) or any other ingredient of Sandoz Azithromycin (see “What are the ingredients in Sandoz Azithromycin?”).
To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Sandoz Azithromycin. Talk about any health conditions or problems you may have, including if you:

- have a known prolonged heart cycle (interval) (QT prolongation)
- are currently taking medication known to prolong QT interval (prolong your heart cycle) such as antiarrhythmics (drugs to regulate your heartbeat such as class IA: quinidine, procainamide and class III: dofetilide, amiodarone, sotalol); antipsychotic agents; antidepressants; and fluoroquinolones (a class of antibiotics)
- have a history of life-threatening irregular heartbeat
- have constantly low levels of potassium or magnesium in your blood
- have a history for heart problems such as slow heart rate, irregular heartbeat or cardiac insufficiency (your heart has a hard time pumping blood to your body)
- have diabetes or hereditary problems of fructose intolerance, glucose-galactose malabsorption or saccharase-isomaltase deficiency, as this product contains sucrose
- are pregnant or think you are pregnant,
- are breastfeeding or planning to breastfeed. Azithromycin has been reported to be excreted in human breast milk. It is not known if Sandoz Azithromycin could affect a baby. Discuss with your doctor.
- have ever had any liver or kidney problems
- have a weak immune system
- have myasthenia gravis (a chronic autoimmune neuromuscular disease which causes muscle weakness)
- are allergic to any medicines including antibiotics such as erythromycin

Other warnings you should know about:
If your child develops diarrhea during or after treatment with Sandoz Azithromycin, tell your child’s doctor at once. Do not use any medicine to treat your child’s diarrhea without first checking with your child’s doctor.

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

If your baby develops projectile vomiting or irritability during feeding, during or after treatment with Sandoz Azithromycin, contact your baby’s doctor at once.

Your child's doctor or nurse can advise you when your child should begin feeling better.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.
The following may interact with Sandoz Azithromycin:

- Warfarin (or other anticoagulant medicine);
- Cyclosporin (used to suppress the immune system to prevent and treat rejection in organ or bone marrow transplants);
- Digoxin (used for treatment of heart problems);
- Nelfinavir (used for treatment of HIV infections);
- Ergotamine and ergot derivatives (used for migraine treatment). Ergotamine and ergot derivatives should not be used with Sandoz Azithromycin.

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 to take Sandoz Azithromycin:**

Your child's doctor will decide the total amount of Sandoz Azithromycin to give to your child, depending on your child's weight and on the specific infection your child has. In addition to deciding the total amount of Sandoz Azithromycin to give to your child, the doctor will tell you to give all the medicine to your child in 1 day or to divide it over 3 days or over 5 days.

Sandoz Azithromycin should be taken once-a-day and may be given with or without food. Shake the bottle well just before you give a dose.

Use the dosing device that comes with Sandoz Azithromycin to carefully measure the dose. Do not use a household teaspoon as it is not accurate enough.

Give Sandoz Azithromycin for the full number of days prescribed by the doctor, even if your child feels better before finishing all the medicine as prescribed.

**Usual dose:**

**For Ear Infections**

For ear infections, your child's doctor will tell you to give Sandoz Azithromycin to your child in one of the following ways:

- the total amount as 1 dose on 1 day or
- once-a-day for 3 days or
- once-a-day for 5 days, with a double dose on the first day.

Whether given all on 1 day, or divided over 3 days or over 5 days, the total amount of Sandoz Azithromycin you give to your child should be the same.

**For Pneumonia**

For pneumonia, your child's doctor will tell you to give Sandoz Azithromycin to your child once-a-day for 5 days, with a double dose on the first day.

**For Throat Infections**

For throat infections, your child's doctor will tell you to give Sandoz Azithromycin to your child in the following way: once-a-day for 5 days. When Sandoz Azithromycin is given for 5 days for
throat infections, you do not need to give a double dose on the first day (as you would with ear infections).

If your child vomits within 30 minutes after the 1-day treatment for an ear infection, it is recommended that you call your pharmacist or child’s doctor because your child may need to receive the same dose of medicine again.

If you have questions about how to give Sandoz Azithromycin to your child, please ask your child’s doctor, nurse or pharmacist.

**Instructions for Use of the Dosing Devices:**
Use only the dosing device provided to measure the correct amount of suspension.

1. To open, push down on the bottle cap while twisting the cap counter clockwise. Remove cap from bottle.

2. Push plastic stopper into bottle top (if pharmacist has not done so).

3. Pull back on syringe handle to prescribed dose.

4. Insert syringe into bottle top.

5. Push down on syringe handle to allow air into bottle.

6. Turn bottle upside down and pull back syringe handle, drawing prescribed dose of medicine into syringe.

7. Remove syringe from bottle.
Give medicine by mouth by slowly pushing on syringe handle.
Remember to put the cap back on the medicine bottle.

**Overdose**

If you think you have taken too much Sandoz Azithromycin, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.
Missed Dose:
If you forget to give your child a dose, call your pharmacist or child’s doctor. Do not double dose.

What are possible side effects from using Sandoz Azithromycin?
These are not all the possible side effects you may feel when taking Sandoz Azithromycin. If you experience any side effects not listed here, contact your healthcare professional.
Side effects may include:
- Diarrhea/loose stools
- Stomach pain
- Nausea and vomiting
- Headache

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**Reporting Side Effects**
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- By calling 1-866-234-2345 (toll-free);
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  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9
  Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**
Sandoz Azithromycin dry powder can be stored at controlled room temperature (15°C-30°C). Protect from light.

**Reconstituted suspension:** Store between 5°C and 30°C. Discard unused portion after 10 days. Throw away any medicine that is left over after treatment.

Keep out of reach and sight of children.

**If you want more information about Sandoz Azithromycin:**
- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer’s website www.sandoz.ca or by calling 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

Last revised: November 10, 2016