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Azithromycin (systemic): Patient drug information

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(For additional information <u>see "Azithromycin (systemic): Drug information"</u> and <u>see "Azithromycin (systemic):</u> <u>Pediatric drug information"</u>)

Brand Names: US

Zithromax; Zithromax Tri-Pak; Zithromax Z-Pak; Zmax [DSC]

Brand Names: Canada

ACT Azithromycin [DSC]; AG-Azithromycin; APO-Azithromycin; APO-Azithromycin Z; AURO-Azithromycin; DOM-Azithromycin; GD-Azithromycin [DSC]; GEN-Azithromycin; JAMP-Azithromycin; M-Azithromycin; Mar-Azithromycin; MYLAN-Azithromycin [DSC]; NRA-Azithromycin; PHL-Azithromycin [DSC]; PMS-Azithromycin; PRO-Azithromycin; RATIO-Azithromycin; RIVA-Azithromycin; SANDOZ Azithromycin; TEVA-Azithromycin; Zithromax

What is this drug used for?

• It is used to treat or prevent bacterial infections.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have turned yellow or had liver side effects with this drug before.

- If you have any of these health problems: Long QTc on ECG or other heartbeat that is not normal, slow heartbeat, or low potassium or magnesium levels.
- If you have heart failure (weak heart).
- If you have ever had a certain type of abnormal heartbeat (torsades de pointes).
- If you are taking any drugs that can cause a certain type of heartbeat that is not normal (prolonged QT interval). There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

For all patients taking this drug:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Do not use longer than you have been told. A second infection may happen.
- A severe and sometimes deadly reaction has happened. Most of the time, this reaction has signs like fever, rash, or swollen glands with problems in body organs like the liver, kidney, blood, heart, muscles and joints, or lungs. If you have questions, talk with the doctor.
- This drug may cause a type of abnormal heartbeat (prolonged QT interval). If this happens, the chance of other unsafe and sometimes deadly abnormal heartbeats may be raised.
- If you have myasthenia gravis, talk with your doctor. Call your doctor if your signs get worse. Signs of myasthenia gravis have also happened in people who do not have it. Call your doctor right away if you have new or worse muscle weakness, trouble chewing or swallowing, trouble breathing, droopy eyelids, or change in eyesight like blurred eyesight or seeing double.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

Newborns:

• A very bad stomach problem has happened in newborns taking this drug. Call the doctor right away if your child throws up or gets irritable with feeding.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Chest pain or pressure, a fast heartbeat, or an abnormal heartbeat.
- Dizziness or passing out.
- Change in hearing.
- Fever.
- Swollen gland.
- Change in eyesight.
- Diarrhea is common with antibiotics. Rarely, a severe form called C diff–associated diarrhea (CDAD) may happen. Sometimes, this has led to a deadly bowel problem. CDAD may happen during or a few months after taking antibiotics. Call your doctor right away if you have stomach pain, cramps, or very loose, watery, or bloody stools. Check with your doctor before treating diarrhea.
- Very bad and sometimes deadly liver problems have happened with this drug. Call your doctor right away if you have signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- A severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause severe health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

<u>All products:</u>

- Headache.
- Stomach pain or diarrhea.
- Upset stomach or throwing up.

Injection:

• Pain where the shot was given.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

<u>Zmax:</u>

- Take this drug on an empty stomach. Take at least 1 hour before or at least 2 hours after a meal.
- Shake well before use.
- Use within 12 hours of making.
- If you throw up within 1 hour of taking this drug, call your doctor to find out what to do.

All other oral products:

- Take with or without food.
- Do not take antacids that have magnesium or aluminum at the same time as this drug. Talk with your doctor or pharmacist.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

Liquid (suspension):

- Shake well before use.
- Measure liquid doses carefully. Use the measuring device that comes with this drug. If there is none, ask the pharmacist for a device to measure this drug.

Packets:

• Empty powder packet in ¹/₄ cup (60 mL) of water. Mix well and drink. Rinse cup with more water and drink.

Injection:

• It is given as an infusion into a vein over a period of time.

What do I do if I miss a dose?

Tablets and liquid (suspension):

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

All other oral products:

• Only 1 dose of this drug is needed. If you miss your dose, take it as soon as you think about it.

Injection:

• Call your doctor to find out what to do.

How do I store and/or throw out this drug?

Liquid (suspension):

- Store liquid (suspension) at room temperature or in a refrigerator. Throw away any unused portion after 10 days.
- Store in original container.
- Keep lid tightly closed.
- Store in a dry place. Do not store in a bathroom.

All other oral products:

• Store at room temperature in a dry place. Do not store in a bathroom.

<u>Zmax:</u>

• After mixing, do not refrigerate or freeze.

Injection:

• If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

<u>All products:</u>

- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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