

Mammalian Cell Gene Mutation Assay: The L5178Y Mouse Lymphoma Assay for gene mutations at the thymidine kinase locus was conducted at concentrations of 36-360 µg/mL to cytotoxicity in the presence and absence of rat liver microsomal enzymes.

***In Vitro* Cytogenetics Assay:** The clastogenic activity of azithromycin was evaluated in human lymphocytes *in vitro* exposed up to toxic concentrations of 40 µg/mL in the presence and 7.5 µg/mL in the absence of rat liver microsomal enzymes.

***In Vivo* Cytogenetics Assay:** Azithromycin was examined for clastogenic activity in the bone marrow cells of male and female CD-1 mice treated orally at 200 mg/kg, and sacrificed at 6, 24 or 48-hours post-treatment.

Antigenicity Studies:

Azithromycin was tested for the induction of a systemic anaphylaxis reaction in guinea pigs and in rabbits. Azithromycin did not have antigenic potential under the conditions used in the studies.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ZITHROMAX

Azithromycin tablets USP

Read this carefully before you start taking ZITHROMAX 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 ZITHROMAX.

What is ZITHROMAX used for?

ZITHROMAX 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, disseminated *Mycobacterium avium* complex (MAC) disease in people with HIV, and pneumonia.

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

How does ZITHROMAX work?

ZITHROMAX 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 ZITHROMAX may be taken for as short a time as one day.

What are the ingredients in ZITHROMAX?

Medicinal ingredients: Azithromycin dihydrate

Non-medicinal ingredients: anhydrous calcium phosphate dibasic, D&C Red #30 aluminum lake (250 mg tablet only), hydroxypropyl methylcellulose, lactose, magnesium stearate, pregelatinized starch, sodium croscarmellose, sodium lauryl sulphate, titanium dioxide and triacetin

ZITHROMAX comes in the following dosage forms:

Tablets: 250 mg, 600 mg

Do not use ZITHROMAX if:

- you have a history of liver problems when you have used azithromycin.
- you are hypersensitive (allergic) to azithromycin, or any macrolide or ketolide antibiotic (including erythromycin) or any other ingredient of ZITHROMAX (see **What are the ingredients in ZITHROMAX?**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZITHROMAX. 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 heart beat 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 heart beat
- 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 breastfeeding or planning to breastfeed. Azithromycin is excreted in human breast milk. It is not known if ZITHROMAX 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 ZITHROMAX for the full number of days your doctor prescribed. Although ZITHROMAX's dosing is short, you should not expect ZITHROMAX to work faster than other antibiotics which are dosed up to 10 days. If you stop taking ZITHROMAX 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 ZITHROMAX, 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 ZITHROMAX:

- 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);
- Colchicine (used for treatment of gout);
- Nelfinavir (used for treatment of HIV infections);
- Ergotamine and ergot derivatives (used for migraine treatment). Ergotamine and ergot derivatives should not be used with ZITHROMAX.

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

How to take ZITHROMAX:

Always take ZITHROMAX as the doctor has prescribed for you, depending on the specific condition you have.

ZITHROMAX can be taken with or without food.

Usual adult dose:

If your doctor prescribes **ZITHROMAX 250 mg tablets** for 3 days for treatment of bronchitis:

Days 1 through 3: Take two tablets each day.

If your doctor prescribes the 5-day **ZITHROMAX Z-PAK 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 **ZITHROMAX 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 **ZITHROMAX 250 mg tablets** for 1 day for treatment of gonococcal urethritis and cervicitis:

Days 1: Take eight tablets once.

If your doctor prescribes **ZITHROMAX 600 mg tablets** for prevention of *Mycobacterium avium* complex (MAC) disease:

Take two tablets once weekly.

Overdose:

If you think you, or a person you are caring for, have taken too much ZITHROMAX, contact a 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 ZITHROMAX?

These are not all the possible side effects you may have when taking ZITHROMAX. If you experience any side effects not listed here, tell 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 | | | |
|---|---|---------------------|--|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| COMMON | | | |

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| <i>Clostridioides difficile</i> colitis (bowel inflammation): severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness | | | √ |
| UNCOMMON | | | |
| Abnormal heart rhythm: feel your heart beating in your chest, abnormal heartbeat, dizziness or feeling faint | | | √ |
| Severe allergic reaction: trouble breathing, swelling of the face, mouth, throat, neck, severe skin rash or blisters | | | √ |
| Liver disorder: abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine | | | √ |
| Myasthenia gravis: muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing | | √ | |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

Store ZITHROMAX at controlled room temperature (between 15-30°C).
Keep out of reach and sight of children.

If you want more information about ZITHROMAX:

- 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: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

Last Revised APRIL 27, 2023

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Azithromycin for oral suspension USP

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What is ZITHROMAX used for?

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

How does ZITHROMAX work?

ZITHROMAX 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 ZITHROMAX may be taken for as short a time as one day.

What are the ingredients in ZITHROMAX?

Medicinal ingredients: Azithromycin dihydrate

Non-medicinal ingredients: artificial flavours, FD&C Red #40, sodium phosphate (8.76 mg per 100 mg/5 mL and 17.50 mg per 200 mg/5 mL), sucrose (3.86 g per 100 mg/5 mL and 3.87 g per 200 mg/5 mL), tribasic hydroxypropyl cellulose and xanthan gum

ZITHROMAX comes in the following dosage forms:

Powder for oral suspension – azithromycin 300, 600, 900 mg/bottle, or 100 mg/5 ml, 200 mg/5 ml when reconstituted (as azithromycin dihydrate)

Do not use ZITHROMAX if:

- you have a history of liver problems when you have used azithromycin.
- you are hypersensitive (allergic) to azithromycin, or any macrolide or ketolide antibiotic (including erythromycin) or any other ingredient of ZITHROMAX (see **What are the ingredients in ZITHROMAX?**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZITHROMAX. 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 heart beat 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 heart beat
- 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)
- 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 is excreted in human breast milk. It is not known if ZITHROMAX 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 ZITHROMAX, 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 ZITHROMAX for the full number of days your child's doctor prescribed. Although ZITHROMAX's dosing is short and you may be able to give all the medicine to your child more easily, you should not expect ZITHROMAX to work faster than other antibiotics which are dosed for up to 10 days. If you stop giving ZITHROMAX 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 ZITHROMAX, 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 ZITHROMAX:

- 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);
- Colchicine (used for treatment of gout);
- Nelfinavir (used for treatment of HIV infections);
- Ergotamine and ergot derivatives (used for migraine treatment). Ergotamine and ergot derivatives should not be used with ZITHROMAX.

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

How to take ZITHROMAX:

Your child's doctor will decide the total amount of ZITHROMAX 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 ZITHROMAX 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.

ZITHROMAX 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 ZITHROMAX to carefully measure the dose. Do not use a household teaspoon as it is not accurate enough.

Give ZITHROMAX 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 ZITHROMAX 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 ZITHROMAX you give to your child should be the same.

For Pneumonia

For pneumonia, your child's doctor will tell you to give ZITHROMAX 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 ZITHROMAX to your child in the following way: once-a-day for 5 days. When ZITHROMAX 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 ZITHROMAX to your child, please ask your child's doctor, nurse or pharmacist.

Instructions for Use of the Dosing Devices:

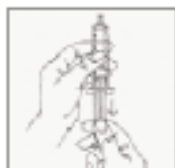
Use only the dosing device provided to measure the correct amount of suspension.



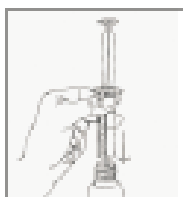
1. To open, push down on the bottle cap while twisting the cap counter clockwise. Remove cap from bottle.



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



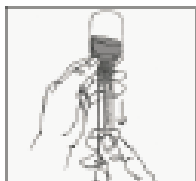
3. Pull back on syringe handle to prescribed dose.



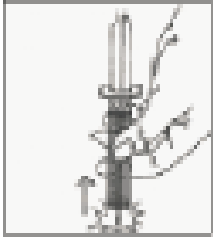
4. Insert syringe into bottle top.



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.

Instructions for Use of the Dosing Cup

If you receive the dosing cup with ZITHROMAX oral suspension shake the bottle well before using. Rinse the cup with water after each daily dose. After your child has taken ZITHROMAX for the correct number of days, throw out the cup, cap, and bottle.



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



2. A label on the bottle shows how much medicine your child must take.



3. Pour medicine into the cup provided. The cup may need to be filled more than once. Depending on your child's dose, there might be some medicine left in the bottle.



4. Give dose to child.
 Make sure child drinks all of the medicine for the number of days instructed by the doctor or pharmacist.
 Remember to put the cap back on the medicine bottle.

Do not save any medicine for future use.

Overdose:

If you think you, or a person you are caring for, have taken too much ZITHROMAX, contact a 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 ZITHROMAX?

These are not all the possible side effects you may have when taking ZITHROMAX. If you experience any side effects not listed here, tell 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 | | | |
|--|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| COMMON | | | |
| <i>Clostridioides difficile</i> colitis (bowel inflammation): severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness | | | √ |
| UNCOMMON | | | |
| Abnormal heart rhythm: feel your heart beating in your chest, | | | √ |

| | | | |
|--|--|---|---|
| abnormal heartbeat, dizziness or feeling faint | | | |
| Severe allergic reaction: trouble breathing, swelling of the face, mouth, throat, neck, severe skin rash or blisters | | | √ |
| Intestinal blockage: Projectile vomiting, irritability during feeding | | | √ |
| Liver disorder: abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine | | | √ |
| Myasthenia gravis: muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing | | √ | |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

ZITHROMAX can be stored in the refrigerator or kept at room temperature (between 5°-30°C). Throw away any medicine that is left over after treatment.

Keep out of reach and sight of children.

If you want more information about ZITHROMAX:

- 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: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

Last Revised APRIL 27, 2023

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ZITHROMAX

Azithromycin for injection USP

Read this carefully before you start taking ZITHROMAX 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 ZITHROMAX.

What is ZITHROMAX used for?

ZITHROMAX is an antibiotic medicine used to treat the following types of **mild to moderate** infections **by certain microorganisms** in adults: genitourinary infections and pneumonia.

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

How does ZITHROMAX work?

ZITHROMAX 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 ZITHROMAX may be taken for as short a time as one day.

What are the ingredients in ZITHROMAX?

Medicinal ingredients: Azithromycin dihydrate

Non-medicinal ingredients: Anhydrous citric acid; sodium hydroxide

ZITHROMAX comes in the following dosage forms:

Azithromycin for injection (as azithromycin dihydrate), 500 mg/vial or 500 mg/5 ml when reconstituted

Do not use ZITHROMAX if:

- you have a history of liver problems when you have used azithromycin.
- you are hypersensitive (allergic) to azithromycin, or any macrolide or ketolide antibiotic (including erythromycin) or any other ingredient of ZITHROMAX (see **What are the ingredients in ZITHROMAX?**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZITHROMAX. 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 heart beat 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 heart beat
- 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 breastfeeding or planning to breastfeed. Azithromycin is excreted in human breast milk. It is not known if ZITHROMAX 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).

Other warnings you should know about:

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

Your healthcare professional will ensure that ZITHROMAX is administered for the full number of days prescribed. If ZITHROMAX is stopped too soon, your infection could come back. The next infection may be worse and be more difficult to treat.

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 ZITHROMAX:

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

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

How to take ZITHROMAX:

ZITHROMAX for Injection will always be prepared and given to you by a doctor or a healthcare professional.

ZITHROMAX for Injection must be reconstituted and diluted as directed, and administered as an intravenous infusion over at least 60 minutes.

Overdose:

If you think you, or a person you are caring for, have taken too much ZITHROMAX, contact a 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 ZITHROMAX?

These are not all the possible side effects you may have when taking ZITHROMAX. If you experience any side effects not listed here, tell 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 | | | |
|---|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| COMMON | | | |
| <i>Clostridioides difficile</i> colitis (bowel inflammation): severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness | | | √ |
| Vaginitis (inflammation of the vagina): change in colour, odor or amount of discharge, itching or irritation, pain during intercourse, painful urination, light vaginal bleeding or spotting | √ | | |
| Injection site reaction: pain, redness and/or swelling at the injection site | | √ | |

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| UNCOMMON | | | |
| Abnormal heart rhythm: feel your heart beating in your chest, abnormal heartbeat, dizziness or feeling faint | | | √ |
| Severe allergic reaction: trouble breathing, swelling of the face, mouth, throat, neck, severe skin rash or blisters | | | √ |
| Liver disorder: abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine | | | √ |
| Myasthenia gravis: muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing | | √ | |

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Storage:

The healthcare professional will store the product under appropriate conditions. Keep out of reach and sight of children.

If you want more information about ZITHROMAX:

- 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: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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