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**APPLICATION OF AZITHROMYCIN AS AN ORAL
SUSPENSION**

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Application of Azithromycin as an Oral Suspension

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Abstract – Azithromycin is used to treat a wide variety of bacterial infections. It is a macrolide-type antibiotic. It works by stopping the growth of bacteria. This medication will not work for viral infections (such as common cold, flu). Unnecessary use or misuse of any antibiotic can lead to its decreased effectiveness. Recited the Patient Information Leaflet if available from your pharmacist before you start taking azithromycin and each time you get a refill. The dosage is based on medical condition and response to treatment. For children, the dose is also based on weight. Shake the suspension well before using. Carefully measure the dose using a special measuring device/spoon. Do not use a household spoon because you may not get the correct dose.

Keywords: - Azithromycin, Antibiotic, Bacterial, Infections.

1. INTRODUCTION

Use Azithromycin Oral Suspension as directed by your doctor. Check the label on the medicine for exact dosing instructions.

- Take Azithromycin Oral Suspension by mouth with or without food. If stomach upset occurs, take with food to reduce stomach irritation.
- Do not take an antacid that has aluminum or magnesium in it within 1 hour before or 2 hours after you take Azithromycin Oral Suspension.
- Shake well before each use.
- Use a measuring device marked for medicine dosing. Ask your pharmacist for help if you are unsure of how to measure your dose.
- Azithromycin Oral Suspension works best if it is taken at the same time each day.
- To clear up your infection completely, take Azithromycin Oral Suspension for the full course of treatment. Keep taking it even if you feel better in a few days.
- If you miss a dose of Azithromycin Oral Suspension, take it as soon as possible. If it is almost time for your next dose, skip the

missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

Ask your health care provider any questions you may have about how to use Azithromycin Oral Suspension.

2. REVIEW OF LITERATURES:

Azithromycin is generally well tolerated. In pediatric clinical trials, the most frequently reported adverse effects were diarrhea (1-6%), abdominal pain (1-4%), nausea (0.5-2%), vomiting (1-6%), headache (1-2%), and rash (0.4-2%). Less common adverse effects included dizziness, agitation, insomnia, fatigue, fever, and constipation, loss of appetite, chest pain, and pruritus. Transient neutropenia was also reported. Discontinuation due to treatment related adverse effects in pediatric clinical trials was approximately 1%. (Zithromax, 2004. Gordon, Blumer, 2004. Dunne, *et al.*, 2003. Dunne, *et al.*, 2003. Arrieta, *et al.*, 2003. Arguedas, *et al.*, 2005. Kogan, *et al.*, 2003. Soni *et al.*, 2004).

Severe allergic reactions have been reported with azithromycin use, including anaphylaxis, angioedema, Stevens Johnson Syndrome, and toxic epidermal necrolysis. Severe cases of cholestatic jaundice have also been associated with azithromycin. (Langley, *et al.*, 2004. Frenck, *et al.*, 2004. Miron, *et al.*, 2004. Kapadia, Talib, 2004. McHugh, *et al.*, 2004). Nephritis has been reported

with azithromycin use, most recently in a case involving a 14 year old girl. (Nahata, *et. al.*, 1993. Nahata, *et. al.*, 1995. Stevens, *et. al.*, 1997. Jacobs, *et. al.*, 2005. Ruuskanen, 2004. Soni, *et. al.*, 2004).

The patient had a serum creatinine concentration of 2.2 mg/dl two weeks after treatment, but slowly recovered. Serum creatinine declined to 0.8 mg/dl. A second course of azithromycin 3 months later produced more significant renal impairment. She recovered without sequelae, and serum creatinine one year after the second episode was 1.2 mg/dl. Azithromycin should be used with caution in patients with known renal or hepatic dysfunction. In addition, as with other antimicrobial agents, pseudomembranous colitis may result from azithromycin use. (Zithromax, 2004. Gordon, Blumer, 2004).

3. IMPORTANT SAFETY INFORMATION:

- Azithromycin Oral Suspension may cause drowsiness, dizziness, blurred vision, or light-headedness. These effects may be worse if you take it with alcohol or certain medicines. Use Azithromycin Oral Suspension with caution. Do not drive or perform other possibly unsafe tasks until you know how you react to it.
- Azithromycin Oral Suspension may cause you to become sunburned more easily. Avoid the sun, sunlamps, or tanning booths until you know how you react to Azithromycin Oral Suspension. Use a sunscreen or wear protective clothing if you must be outside for more than a short time.
- Mild diarrhea is common with antibiotic use. However, a more serious form of diarrhea (pseudomembranous colitis) may rarely occur. This may develop while you use the antibiotic or within several months after you stop using it. Contact your doctor right away if stomach pain or cramps, severe diarrhea, or bloody or watery stools occur. Do not treat diarrhea without first checking with your doctor.
- Tell your doctor or dentist that you take Azithromycin Oral Suspension before you receive any medical or dental care, emergency care, or surgery.
- Severe and sometimes fatal liver problems have been reported with the use of this medicine. Contact your doctor immediately if you develop symptoms of liver problems (eg, yellowing of the skin or eyes; dark urine; pale stools; severe or persistent nausea, vomiting, or loss of appetite; unusual itching). Discuss any questions or concerns with your doctor.
- Long-term or repeated use of Azithromycin Oral Suspension may cause a second infection. Tell your doctor if signs of a second infection occur. Your medicine may need to be changed to treat this.
- Be sure to use Azithromycin Oral Suspension for the full course of treatment. If you do not, the medicine may not clear up your infection completely. The bacteria could also become less sensitive to this or other medicines. This could make the infection harder to treat in the future.
- Azithromycin Oral Suspension only works against bacteria; it does not treat viral infections (eg, the common cold).
- Use Azithromycin Oral Suspension with caution in the elderly; they may be more sensitive to its effects, especially irregular heartbeat.
- Azithromycin Oral Suspension should be used with extreme caution in children younger than 6 months old; safety and effectiveness in these children have not been confirmed.
- Pregnancy and Breast-feeding: If you become pregnant, contact your doctor. You will need to discuss the benefits and risks of using Azithromycin Oral Suspension while you are pregnant. It is not known if this medicine is found in breast milk. If you are or will be breast-feeding while you take Azithromycin Oral Suspension, check with your doctor. Discuss any possible risks to your baby.

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to azithromycin or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

“Safety and efficacy have not been established for the treatment of sinusitis in pediatric patients or for infants younger than 6 months of age. Appropriate studies have not been performed on the relationship of age to the effects of azithromycin to treat sinusitis in children or to treat pneumonia in children younger than 6 months of age.

Appropriate studies have not been performed on the relationship of age to the effects of azithromycin *oral*

suspension and tablets to treat pharyngitis or tonsillitis in children younger than 2 years of age. Safety and efficacy have not been established.”

Geriatric

“Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of azithromycin in the elderly. However, elderly patients are more likely to have heart rhythm problems (e.g., torsade’s de pointes) which may require caution in patients receiving azithromycin.”

Interactions with Food/Tobacco/Alcohol

“Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.”

CONCLUSION:

The concurrent use of antacids with azithromycin may reduce peak serum concentrations, but does not appear to affect overall absorption. Administration of azithromycin with nelfinavir has resulted in increased azithromycin serum concentrations. There is a case report suggesting that azithromycin may increase serum concentrations of cyclosporine when the two drugs are given together. Patients receiving this combination should be closely monitored. Use of azithromycin in patients receiving HMG-CoA reductase inhibitors may be at increased risk for myopathy or rhabdomyolysis. (Zithromax, 2004. Gordon, Blumer, 2004).

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