Only for the use of medical professionals

Odazyth®

Azithromycin

Description:

Odazyth® is a preparation of Azithromycin, which is an azalide antibiotic, a subclass of macrolide antibiotic. Azithromycin is active against wide range of Gram-positive and Gram-negative organisms. It acts by binding to the 50s ribosomal subunit of susceptible microorganisms and thus interfering with microbial protein synthesis.

Indications and Uses:

Odazyth® tablet and suspension is indicated for the treatment of patients with infections caused by susceptible organisms in:

Adults:

- Acute bacterial exacerbations of chronic obstructive pulmonary disease due to *Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae.*
- Acute bacterial sinusitis due to *Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae.*
- Community-acquired pneumonia due to *Chlamydia pneumoniae, Haemophilus influenzae, Mycoplasma pneumoniae or Streptococcus pneumoniae* in patients appropriate for oral therapy.
- Pharyngitis/Tonsillitis caused by *Streptococcus pyogenes* as an alternative to first-line therapy in individuals who cannot use first-line therapy.
- Uncomplicated skin and skin structure infections due to *Staphylococcus aureus, Streptococcus pyogenes,* or *Streptococcus agalactiae.* Abscesses usually require surgical drainage.
- Urethritis and cervicitis due to *Chlamydia trachomatis* or *Neisseria gonorrhoeae*
- Genital ulcer disease in men due to *Haemophilus ducreyi* (chancroid).

Children:

- Acute otitis media caused by *Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae.*
- Community-acquired pneumonia due to *Chlamydia pneumoniae, Haemophilus influenzae, Mycoplasma pneumoniae or Streptococcus pneumoniae* in patients appropriate for oral therapy.
- Pharyngitis/Tonsillitis caused by *Streptococcus pyogenes* as an alternative to first-line therapy in individuals who cannot use first-line therapy.

Dosage and Administration:

Odazyth® tablet and capsule for adult

Infection	**Recommended dose and duration of therapy**
Community-acquired pneumonia (mild severity) Pharyngitis/Tonsillitis (second line therapy) Skin/skin structure (uncomplicated)	500 mg as a single dose on day 1, followed by 250 mg once daily on days 2 through 5.
Acute bacterial exacerbations of chronic obstructive pulmonary disease (mild to moderate)	500 mg once daily for 3 days or 500 mg as a single dose on Day 1, followed by 250 mg once daily on Days 2 through 5.
Acute bacterial sinusitis	500 mg once daily for 3 days
Genital ulcer disease (chancroid)	1 g as a single dose
Non-gonoccocal urethritis and cervicitis	1 g as a single dose
Gonococcal urethritis and cervicitis	2 g as a single dose

Odazyth® oral suspension for children

Infection	**Recommended dose and duration of therapy**
Acute otitis media	30 mg/kg (0.75ml/kg) given as a single dose or 10 mg/kg (0.25ml/kg) once daily for 3 days or 10 mg/kg (0.25ml/kg) as a single dose on the first day followed by 5 mg/kg/day (0.125ml/kg/day) on days 2 through 5
Acute bacterial sinusitis	10 mg/kg (0.25ml/kg) once daily for 3 days
Community-acquired pneumonia	10 mg/kg (0.25ml/kg) as a single dose on the first day followed by 5 mg/kg (0.125ml/kg) on days 2 through 5
Pharyngitis/Tonsillitis	12 mg/kg (0.3ml/kg) once daily for 5 days

Directions for Reconstitution of Suspension

Shake the bottle well before mixing the water. **15 ml suspension:** Add 10 ml boiled and cooled water for 15 ml; **30 ml suspension:** Add 20 ml boiled and cooled water for 30 ml; **50 ml suspension:** Add 33.5 ml boiled and cooled water for 50 ml to the dry powder of the bottle. Use the supplied dropper or spoon for water measurement. Shake till powder is completely mixed with water. Keep the prepared suspension in cool dry place and consume within 5 days of preparation. Shake the bottle well before use.

Use in Pregnancy and Lactation:

Azithromycin should be used during pregnancy only if clearly needed. Recent clinical studies have recommended that Azithromycin should be considered for the initial treatment of *chlamydial cervicitis* in pregnancy. It is not known whether Azithromycin is excreted in human milk. Caution should be exercised when Azithromycin is administered to a nursing woman.

Contraindications

Azithromycin is contra-indicated in patients with a known hypersensitivity to Azithromycin or any of the macrolide antibiotics. Because of the theoretical possibility of ergotism, Azithromycin and ergot derivatives should not be co-administered.

As liver is the principal route of excretion of Azithromycin, it should not be used in patients with hepatic disease.

Precautions

Azithromycin is eliminated via liver; caution should be taken in patient with impaired hepatic function. Caution should be taken in sever renal impairment. As with any antibiotic, observation for signs of super infection with non-susceptible organisms, including fungi, is recommended. Azithromycin should not be concomitantly used with astemizole or terfenadine.

Side Effects:

Azithromycin is well tolerated with a low incidence of side effects. Most side effects observed were mild to moderate in severity.

The majority of side effects were gastro intestinal in origin with nausea, abdominal discomfort (pain/cramps), vomiting, flatulence, diarrhea and loose stools being occasionally observed. Allergic reactions such as rash have occurred which are reversible upon discontinuation of therapy.

Transient mild reductions in neutrophil counts have occasionally been observed in clinical trials, although a causal relationship to Azithromycin has not been established.

Drug Interactions

Azithromycin absorption is reduced in presence of food and antacid. So, Azithromycin should be administered at least 1 hour before or 2 hours after the antacid and food taken. Macrolides have been known to increase the plasma concentration of digoxin and cyclosporine. Therefore if co-administration is necessary caution should be exercised and serum levels of digoxin and cyclosporine checked. There have been no pharmacokinetic drug interactions between Azithromycin and warfarin, theophyline, carbamazepine, methylprednisolone and cimetidine.

Over dosage

There are no data on over dosage with Azithromycin. Typical symptoms of over dosage with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhea. Gastric lavage and general supportive measures are indicated.

Pharmaceutical Precautions:

Odazyth® tablet , capsule and powder for suspensions should be stored in a cool dry place. The reconstituted suspension should be stored at room temperature and any used suspension discarded after 5 days.

Presentation:

Odazyth® 250 mg capsule: Each capsule contains Azithromycin 250 mg as Dihydrate USP.

Odazyth® 500 mg tablet: Each tablet contains Azithromycin 500 mg as Dihydrate USP.

Odazyth® 15 ml, 30 ml & 50 ml powder for suspension: After reconstitution each 5 ml suspension contains Azithromycin 200 mg as Dihydrate USP.

Package Quantities:

Odazyth® 250 mg capsule: Carton of 6's capsules in blister (for export only).

Odazyth® 500 mg tablet: Carton of 3's, 6's & 9's tablets in blister (for export only).

Odazyth® 500 mg tablet: Carton of 12's tablets in blister.

Odazyth® powder for suspension: Bottle of 15 ml, 30 ml & 50 ml.

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