Bosch

For Medical Professional only

ZEZOT®

500mg Injection

زیزوٹ ۵۰۰ ملی گرام انجکشن

(ایزیتھرومائیسن)

(Azithromycin)

(Product Specs.: U.S.P)

DESCRIPTION

ZEZOT contain the active ingredient azithromycin, a macrolide antibacterial drug, for intravenous administration. Azithromycin has the chemical name (2R,3S,4R,5R,8R,10R, 11R,12S,13S,14R)-13-[(2,6-dideoxy-3-C-methyl-3-O-methyl-α-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]- 1- oxa-6-azacyclopentadecan-15-one. Azithromycin is derived from erythromycin; however, it differs chemically from erythromycin in that a methyl-substituted nitrogen atom is incorporated into the lactone ring. Azithromycin, as the dihydrate, is a white crystalline powder with a molecular formula of $C_{38}H_{72}N_2O_{12}$•$2H_2O$ and a molecular weight of 785.0.

COMPOSITION:

Each vial contains :
Azithromycin U.S.P. 500mg
as Azithromycin dihydrate
(Product Specs.: U.S.P.)

Clinical Pharmacology:

Pharmacodynamic Properties:

Pharmacotherapeutic group: Antibacterial for systemic use, macrolides. ATC code: J01FA10.

Mechanism of Action:

Azithromycin acts by binding to the 23S rRNA of the 50S ribosomal subunit of susceptible microorganisms inhibiting bacterial protein synthesis and impeding the assembly of the 50S ribosomal subunit.

INDICATIONS AND USAGE

ZEZOT (azithromycin for injection) is indicated for the treatment of patients with infections caused by susceptible strains of the designated microorganisms in the conditions listed below. As recommended dosages, durations of therapy, and applicable patient populations vary among these infections.

Community-acquired pneumonia due to Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Moraxella catarrhalis, Mycoplasma pneumoniae, Staphylococcus aureus, or Streptococcus pneumoniae in patients who require initial intravenous therapy.

Pelvic inflammatory disease due to Chlamydia trachomatis, Neisseria gonorrhoeae, or Mycoplasma hominis in patients who require initial intravenous therapy. If anaerobic microorganisms are suspected of contributing to the infection, an antimicrobial agent with anaerobic activity should be administered in combination with ZEZOT.

CONTRAINDICATIONS

ZEZOT is contraindicated in patients with known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide antibiotic.

PRECAUTIONS

General: Because azithromycin is principally eliminated via the liver, caution should be exercised when azithromycin is administered to patients with impaired hepatic function. Due to the limited data in subjects with GFR <10 mL/min, caution should be exercised when prescribing azithromycin in these patients. ZEZOT (azithromycin for injection) should be reconstituted and diluted as directed and administered as an intravenous infusion over not less than 60 minutes. Local I.V. site reactions have been reported with the intravenous administration of azithromycin. The incidence and severity of these reactions were the same when 500 mg azithromycin were given over 1 hour (2 mg/mL as 250 mL infusion) or over 3 hours (1 mg/mL as 500 mL infusion). All volunteers who received infusate concentrations above 2.0 mg/mL experienced local I.V. site reactions and, therefore, higher concentrations should be avoided. Prolonged cardiac repolarization and QT interval, imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in treatment with other macrolides. A similar effect with azithromycin cannot be completely ruled out in patients at increased risk for prolonged cardiac repolarization. Exacerbation of symptoms of myasthenia gravis and new onset of myasthenic syndrome have been reported in patients receiving azithromycin therapy. Prescribing ZEZOT (azithromycin) in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have not been performed to evaluate carcinogenic potential. Azithromycin has shown no mutagenic potential in standard laboratory tests: mouse lymphoma assay, human lymphocyte clastogenic assay, and mouse bone marrow clastogenic assay. No evidence of impaired fertility due to azithromycin was found.

Pregnancy: Teratogenic Effects. Pregnancy Category B: There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, azithromycin should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether azithromycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when azithromycin is administered to a nursing woman.

ADVERSE REACTIONS

Clinical side effects leading to discontinuations from these studies were most commonly gastrointestinal (abdominal pain, nausea,

vomiting, diarrhea), and rashes; laboratory side effects leading to discontinuation were increases in transaminase levels and/or alkaline phosphatase levels. Overall, the most common side effects associated with treatment in adult patients who received I.V./P.O. ZEZOT in studies of community-acquired pneumonia were related to the gastrointestinal system with diarrhea/loose stools (4.3%), nausea (3.9%), abdominal pain (2.7%), and vomiting (1.4%) being the most frequently reported. Approximately 12% of patients experienced a side effect related to the intravenous infusion; most common were pain at the injection site (6.5%) and local inflammation (3.1%). The most common side effects associated with treatment in adult women who received I.V./P.O. Azithromycin in studies of pelvic inflammatory disease were related to the gastrointestinal system. Diarrhea (8.5%) and nausea (6.6%) were most commonly reported, followed by vaginitis (2.8%), abdominal pain (1.9%), anorexia (1.9%), rash and pruritus (1.9%). When azithromycin was coadministered with metronidazole in these studies, a higher proportion of women experienced side effects of nausea (10.3%), abdominal pain (3.7%), vomiting (2.8%), application site reaction, stomatitis, dizziness, or dyspnea (all at 1.9%). No other side effects occurred in patients on the multiple dose I.V./P.O. regimen of Azithromycin in these studies with a frequency greater than 1%. Side effects that occurred with a frequency of 1% or less included the following:
Gastrointestinal: dyspepsia, flatulence, mucositis, oral moniliasis, and gastritis, **Nervous System:** headache, somnolence
Allergic: bronchospasmm **Special Senses:** taste perversion

DOSAGE AND ADMINISTRATION
The recommended dose of ZEZOT (azithromycin for injection) for the treatment of adult patients with community-acquired pneumonia due to the indicated organisms is: 500 mg as a single daily dose by the intravenous route for at least two days. Intravenous therapy should be followed by azithromycin by the oral route at a single, daily dose of 500 mg, administered as two 250-mg tablets to complete a 7 to 10 day course of therapy. The timing of the switch to oral therapy should be done at the discretion of the physician and in accordance with clinical response. The recommended dose of ZEZOT (azithromycin) for the treatment of adult patients with pelvic inflammatory disease due to the indicated organisms is: 500 mg as a single daily dose by the intravenous route for one or two days. Intravenous therapy should be followed by azithromycin by the oral route at a single, daily dose of 250 mg to complete a 7-day course of therapy. ZEZOT (azithromycin for injection) should not be given as a bolus or as an intramuscular injection.

Reconstitution
Prepare the initial solution of ZEZOT (azithromycin for injection) by adding 5 mL of Sterile Water for Injection to the 500 mg vial and shaking the vial until all of the drug is dissolved. Since ZEZOT (azithromycin for injection) is supplied under vacuum, it is recommended that a standard 5 mL (non-automated) syringe be used to ensure that the exact amount of 5 mL of Sterile Water is dispensed. Each mL of reconstituted solution contains 100 mg azithromycin. Reconstituted solution is stable for 24 hours when stored below 30°C or 86°F. Parenteral drug products should be inspected visually for particulate matter prior to administration. If particulate matter is evident in reconstituted fluids, the drug solution should be discarded.

Dilute this solution further prior to administration as instructed below.
Dilution To provide azithromycin over a concentration range of 1.0-2.0 mg/mL, transfer 5 mL of the 100 mg/mL azithromycin solution into the appropriate amount of any of the diluents listed below:
Normal Saline (0.9% sodium chloride)
1/2 Normal Saline (0.45% sodium chloride)
5% Dextrose in Water
Lactated Ringer's Solution
5% Dextrose in 1/2 Normal Saline (0.45% sodium chloride) with 20 mEq KCl
5% Dextrose in Lactated Ringer's Solution
5% Dextrose in 1/3 Normal Saline (0.3% sodium chloride)
5% Dextrose in 1/2 Normal Saline (0.45% sodium chloride)
Normosol®-M in5% Dextrose
Normosol®-R in 5% Dextrose

It is recommended that a 500-mg dose of ZEZOT (azithromycin for injection), diluted as above, be infused over a period of not less than 60 minutes.
ZEZOT (azithromycin for injection) should not be given as a bolus or as an intramuscular injection.
Other intravenous substances, additives, or medications should not be added to ZEZOT (azithromycin for injection), or infused simultaneously through the same intravenous line.

STORAGE AND DIRECTIONS:
Dry powder store at controlled room temperature (15-30^{O}C). When diluted according to the instructions (1.0 mg/mL to 2.0 mg/mL), ZEZOT (azithromycin for injection) is stable for 24 hours at or below 30°C, or for 72 hrs. if stored under refrigeration 5°C .
Add provided Solvent to prepare solution.
For single use only. Discard any unused portion after use.

Dosage: As directed by the physician.
Protect from heat, sunlight and moisture. Keep out of the reach of children.
The expiration date refer to the product correctly stored at the required condition.
Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.
To be sold on prescription of a registered medical practitioner only.

HOW SUPPLIED
ZEZOT (Azithromycin for injection) is supplied in lyophilized powder form under a vacuum in a 8ml vial equivalent to 500 mg of azithromycin for intravenous administration with 1 ampoule of 5ml sterile water for injection.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:۔
دھوپ، گرمی اور نمی سے محفوظ رکھیں۔ بچّوں کی پہنچ سے دُور رکھیں۔
صرف معتمد ڈاکٹر کے نسخے پر فروخت کے لئے۔

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