Aziscot Tablets & Suspension

ایزی سکاٹ ٹیبلیٹس اور سسپینشن

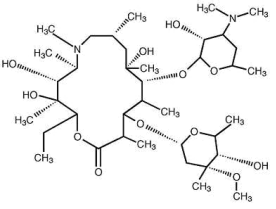
COMPOSITION

Each film coated tablet contains: Azithromycin as dihydrate USP ..... 250 mg & 500mg

Each 5ml suspension contains: Azithromycin as dihydrate USP ..... 200 mg (when prepared as directed)

DESCRIPTION

AZISCOT (azithromycin tablets and azithromycin for oral suspension) contain the active ingredient azithromycin, a macrolide antibacterial drug, for oral administration. Azithromycin is derived from erythromycin; however, it differs chemically from erythromycin in that a methyl-substituted nitrogen atom is incorporated into the lactone ring. Its molecular formula is C38H72N2O12, and its molecular weight is 749.00. Azithromycin has the following structural formula:



CLINICAL PHARMACOLOGY

Mechanism of Action:

Azithromycin is a macrolide antibacterial drug. It 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.

Pharmacodynamics:

Based on animal models of infection, the antibacterial activity of azithromycin appears to correlate with the ratio of area under the concentration-time curve to minimum inhibitory concentration (AUC/MIC) for certain pathogens (*S. pneumoniae* and *S. aureus*).

Pharmacokinetics: ***Absorption:*** The absolute bioavailability of azithromycin is 38%. ***Distribution:*** The serum protein binding of azithromycin is variable in the concentration range approximating human exposure, decreasing from 51% at 0.02 mcg/mL to 7% at 2 mcg/mL. ***Metabolism:*** *In vitro* and *in vivo* studies to assess the metabolism of azithromycin have not been performed. ***Elimination***: Plasma concentrations of azithromycin following single 500 mg oral and IV doses declined in a polyphasic pattern resulting in a mean apparent plasma clearance of 630 mL/min and terminal elimination half-life of 68 hr. Biliary excretion of azithromycin, predominantly as unchanged drug, is a major route of elimination. Over the course of a week, approximately 6% of the administered dose appears as unchanged drug in urine.

INDICATIONS AND USAGE

AZISCOT is a macrolide antibacterial drug indicated for mild to moderate infections caused by designated, susceptible bacteria:

- Acute bacterial exacerbations of chronic bronchitis in adults
- Acute bacterial sinusitis in adults
- Uncomplicated skin and skin structure infections in adults
- Urethritis and cervicitis in adults
- Genital ulcer disease in men
- Acute otitis media in pediatric patients
- Community-acquired pneumonia in adults and pediatric patients
- Pharyngitis/tonsillitis in adults and pediatric patients

Limitation of Use: Azithromycin should not be used in patients with pneumonia who are judged to be inappropriate for oral therapy because of moderate to severe illness or risk factors. To reduce the development of drug-resistant bacteria and maintain the effectiveness of AZISCOT (azithromycin) and other antibacterial drugs, AZISCOT (azithromycin) should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

CONTRAINDICATIONS

- Patients with known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide drug.
- Patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin

WARNINGS AND PRECAUTIONS

- Serious (including fatal) allergic and skin reactions: Discontinue AZISCOT if reaction occurs.
- Hepatotoxicity: Severe, and sometimes fatal, hepatotoxicity has been reported, Discontinue AZISCOT immediately if signs and symptoms of hepatitis occur.
- Infantile Hypertrophic Pyloric Stenosis (IHPS): Following the use of azithromycin in neonates (treatment up to 42 days of life), IHPS has been reported. Direct parents and caregivers to contact their physician if vomiting or irritability with feeding occurs.
- Prolongation of QT interval and cases of torsades de pointes have been reported. This risk which can be fatal should be considered in patients with certain cardiovascular disorders including known QT prolongation or history torsades de pointes, those with proarrhythmic conditions, and with other drugs that prolong the QT interval.
- *Clostridium difficile*-Associated Diarrhea: Evaluate patients if diarrhea occurs.
- AZISCOT may exacerbate muscle weakness in persons with myasthenia gravis.

ADVERSE REACTIONS

Most common adverse reactions are diarrhea (5 to 14%), nausea (3 to 18%), abdominal pain (3 to 7%), or vomiting (2 to 7%).

DRUG INTERACTIONS

- Nelfinavir: Close monitoring for known adverse reactions of azithromycin, such as liver enzyme abnormalities and hearing impairment, is warranted.
- Warfarin: Use with azithromycin may increase coagulation times; monitor prothrombin time.

USE IN SPECIFIC POPULATIONS

- Pediatric use: Safety and e fectiveness in the treatment of patients under 6 months of age have not been established.
- Geriatric use: Elderly patients may be more susceptible to development of torsades de pointes arrhythmias.

USE IN SPECIFIC POPULATIONS

- Pediatric use: Safety and effectiveness in the treatment of patients under 6 months of age have not been established.
- Geriatric use: Elderly patients may be more susceptible to development of torsades de pointes arrhythmias.

DOSAGE AND ADMINISTRATION

- Adult Patients

Infection	Recommended Dose / 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 bronchitis (mild to moderate)	500 mg as a single dose on Day 1, followed by 250 mg once daily on Days 2 through 5 or 500 mg once daily for 3 days.
Acute bacterial sinusitis	500 mg once daily for 3 days.
Genital ulcer disease (chancroid) Non-gonococcal urethritis and cervicitis	One single 1 gram dose.
Gonococcal urethritis and cervicitis	One single 2 gram dose.

- **Pediatric Patients**

Infection	Recommended Dose / Duration of Therapy
Acute otitis media	30 mg/kg as a single dose or 10 mg/kg once daily for 3 days or 10 mg/kg as a single dose on Day 1 followed by 5 mg/kg/day on Days 2 through 5.
Acute bacterial sinusitis	10 mg/kg once daily for 3 days.
Community-acquired pneumonia	10 mg/kg as a single dose on day 1 followed by 5mg/kg once daily on days 2 through 5.
Pharyngitis/tonsillitis	12 mg/kg once daily for 5 days.

As a general guide for prescribing in children, the following daily doses in terms of volume of Aziscot Suspension are suggested:

For children weighing less than 15 kg (over 6 months)	
10 mg/kg once daily (max. 500 mg once daily) for 3 days.	
For children weighing more than 15 kg	
15-25 kg (3-7 years)	5 ml for 3 days
26-35 kg (8-11 years)	7.5 ml for 3 days
36-45 kg (12-14 years)	10 ml for 3 days

There is no information on children less than 6 months of age.

PRESENTATION

AZISCOT 250mg & 500mg Tablets are available in packing containing 6 film coated tablets.
AZISCOT 200mg/5ml Suspension is available in packing containing 30 ml suspension with a bottle containing premium hygienic water for reconstitution and TWIN PACK of Aziscot Suspension is available in a bottle (approx. 30 ml when prepared as directed).
Complete Medical Information available only for doctors on request.

خوراک: ڈاکٹر کی ہدایت کے مطابق۔ احتیاط: روشنی، نمی اور گرمی سے بچائیں۔ 15 سے 30 ڈگری سینٹی گریڈ کے درمیان محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔ مستند ڈاکٹر کے نسخہ پر فروخت اور استعمال کریں۔

scotmann

Manufactured by: **Scotmann Pharmaceuticals**
5-D, I-10/3 Industrial Area, Islamabad-Pakistan
www.scotmann.com