پلازو

(ایزتھرومائسین)

ایزتھرومائسین(پلازو - Plazo) ایک ایسا کیمیائی جُز ہے جو بہت سی اقسام کے جراثیم کے خلاف موثر ہے۔

پلازو (Plazo) مندرجہ ذیل انفیکشنز میں استعمال کی جاسکتی ہے۔

☆ بالائی اور زیریں نظام تنفس کے انفیکشنز مثلاً کان کے درمیانے حصے(Otitis media)، سائنوسائٹس (Sinusitis)، ٹونسیلائیٹس(Tonsillitis)، فیرنجائیٹس(Pharyngitis)، برونکائٹس(Bronchitis) اور نمونیا (Pneumonia)میں۔

☆ جلد اور سافٹ ٹشو(Skin & soft tissue) کے انفیکشنز میں۔

خوراک اور طریقہ استعمال :

بالغ افراد میں پلازو (Plazo) ۵۰۰ ملی گرام ایک مرتبہ روزانہ تین دن تک یا

۵۰۰ ملی گرام پہلے دن اور ۲۵۰ ملی گرام ایک مرتبہ روزانہ دوسرے سے پانچویں دن تک دی جاسکتی ہے۔

چھ ماہ سے زائد عمر کے بچوں میں ۱۰ ملی گرام / کلوگرام ایک مرتبہ روزانہ تین دن تک۔

خاص ھدایات :

پلازو (Plazo) گولیاں کھانے کے ساتھ یا کھانا کھائے بغیر بھی لی جاسکتی ہیں۔

غیر ضروری علامات :

پلازو (Plazo) عموماً ایک محفوظ دوا ہے مگر ہو سکتا ہے کہ کبھی کبھی کچھ مریض مندرجہ ذیل غیر ضروری علامات محسوس کریں جیسے متلی، اُلٹیاں، دست، پیٹ میں درد/مروڑ، زیش اور سر میں درد وغیرہ۔ ایسی صورت میں اپنے ڈاکٹر سے مشورہ کریں۔

ممنوعات / احتیاط :

ایسے مریض جو ایزتھرومائسین یا کسی بھی Macrolide antibiotics سے حساسیت رکھتے ہوں پلازو (Plazo) کا استعمال نہ کریں۔

جگر کی بیماریوں میں مبتلا مریضوں کو ایزتھرومائسین استعمال نہیں کرنی چاہیئے۔

حاملہ اور دودھ پلانے والی خواتین پلازو (Plazo) اپنے ڈاکٹر کے مشورے کے مطابق استعمال کریں۔

سسپینشن تیار کرنے کا طریقہ:

لیبل پر دی گئی ہدایت کے مطابق تیار کریں۔

تیار شدہ سسپینشن دس (۱۰) دن تک استعمال کیا جاسکتا ہے۔

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر خشک جگہ پر رکھیں، روشنی سے بچائیں۔

ڈھکن کو اچھی طرح بند رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔

بچوں کی پہنچ سے دُور رکھیں۔

Manufactured by:

Platinum
Pharmaceuticals (Pvt) Ltd.

A-20, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

QAR NO. AW21-0762

PLAZO

(Azithromycin)

Composition
Plazo Tablets 250 mg
Each film-coated tablet contains
Azithromycin dihydrate (U.S.P.)
equivalent to Azithromycin base ..... 250 mg
Product Complies U.S.P. Specs.

Plazo Tablets 500 mg
Each film-coated tablet contains
Azithromycin dihydrate (U.S.P.)
equivalent to Azithromycin base ..... 500 mg
Product Complies U.S.P. Specs.

Plazo Suspension 200 mg / 5 ml
Each 5 ml contains
Azithromycin dihydrate (U.S.P.)
equivalent to Azithromycin base ..... 200 mg
Product Complies U.S.P. Specs.

Properties
Azithromycin is an azalide, derived from the macrolide class of antibiotics. PLAZO demonstrates activity in vitro, against a wide range of Gram-positive and Gram-negative bacteria including *Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes* (Group A) and other *streptococcal species; influenzae and para-influenzae; Moraxella catarrhalis; anaerobes including Bacteroides fragilis; Escherichia coli; Bordetella pertussis; Bordetella parapertussis; Borrelia burgdorferi; Haemophilus ducreyi; Neisseria gonorrhoeae and Chiamydia trachomatis.* PLAZO also demonstrates in *vitro* activity against *Legionella pneumophila; Mycoplasma pneumoniae and hominis; Campylobacter sp; Toxoplasma gondii* and *Treponema pallidum.*

Pharmacokinetics
Following oral administration in humans, PLAZO is widely distributed throughout the body; bioavailability is approximately 37%. The time taken to peak plasma levels is 2-3 hours. Plasma terminal elimination half-life closely reflects the tissue depletion half-life of 2 to 4 days. Kinetic studies have shown markedly higher PLAZO levels in tissue than in plasma (up to 50 times the maximum observed concentration in plasma) indicating that the drug is highly tissue bound. Concentrations in target tissue such as lung, tonsil and prostate exceed the MIC_{90}-for likely pathogens after a single dose of 500 mg.

Indications
PLAZO is indicated for infections caused by susceptible organisms; in upper & lower respiratory tract infections including otitis media, sinusitis, tonsillitis, pharyngitis,bronchitis and pneumonia.Skin & soft tissue infections. In sexually transmitted diseases in men and women, PLAZO is indicated in the treatment of uncomplicated genital infections due to Chlamydia trachomatis.

Dosage and Administration
PLAZO tablets should be administered as a single dose.
PLAZO tablets can be taken with or without food.
PLAZO suspension should be given at least 1 hour before or 2 hours after meal.

Adults
For all indications except sexually transmitted diseases, the total dose is 1.5 g which should be given as 500 mg as a single dose daily for 3 days. Alternatively an initial dose of 500 mg in the first day may be followed by 250 mg daily for further 4 days.

For sexually transmitted diseases caused by Chlamydia trachomatis the dose is 1 g given as a single dose.

Use in elderly
Normal adult dose is recommended.

D2C

PGL - 1427 (790)

Platinum
Pharmaceuticals (Pvt.) Ltd.

Product : Plazo
Components : Plazo Leaflet

Dimension : 85 mm x 145 mm
Started Date : 04-02-2013
Modified Date: 20-05-2021
Concepts By : Sana
Design By : Rahil Rahim
QAR No. AW21-0762
Supersedes : AW17-0368

Colors

Pantone black C

Department	Marketing	PRO.	Regulatory	Qulity Control	Quality Control Head	Procurement
Remarks						
Signature						
Date / Time						

Use in children
There is no information of children under six months of age. The dose in children is 10 mg / kg as a single daily dose for 3 days.

Dosage Schedule

Body Weight	Age	Dose (Mg)	TSF* / Day	Duration
15-25 kg	3-7 years	200 mg OD	One TSF	3 Days
26-35 kg	8-11 years	300 mg OD	One & half TSF	3 Days
36-45 kg	12-14 years	400 mg OD	Two TSF	3 Days

* One TSF = 5 ml measures provided.

For body weight over 45 kg; normal adult dosage is recommended.

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

Precautions and Warnings
As with any antibiotic, observation for signs of super infection with non-susceptible organisms, including fungi is recommended. As with erythromycin and other macrolides, serious allergic reactions, including angioneurotic oedema and anaphylaxis, have been reported. Some of these reactions with PLAZO have resulted in recurrent symptoms and required a long period of observation and treatment.

Use in renal impairment
No dosage adjustment is needed in patients with mild renal impairment (Creatinine Clearance >40 ml / min.) but there is no data regarding PLAZO usage in patients with more severe renal impairment, thus caution should be exercised in using PLAZO in these patients.

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

Use during pregnancy and lactation
Pregnancy
Animal reproduction studies have demonstrated that PLAZO crosses the placenta, but have revealed no evidence of harm to the foetus. There are no adequate and well-controlled studies in pregnant women. Since animal reproduction studies are not always predictive of human response, PLAZO should be used during pregnancy only if adequate alternatives are not available.

Lactation
No data on secretion of PLAZO in breast milk is available, so PLAZO should only be used in lactating women where adequate alternatives are not available.

Drug interactions
Antacids
In patients receiving PLAZO and antacids, PLAZO should be taken at least 1 hour before or 2 hours after the antacid.

Carbamazepine
In a pharmacokinetics interaction study in healthy volunteers, no significant effect was observed on the plasma levels of carbamazepine or its active metabolite.

Cyclosporin
Some of the related macrolide antibiotics interfere with the metabolism of cyclosporin in the absence of pharmacokinetics studies or clinical data investigating potential interaction between PLAZO and cyclosporin, caution should be exercised before co-administration of these two drugs. If co-administration is necessary, cyclosporin levels should be monitored and the dose adjusted accordingly.

Digoxin
No interactions have been reported in patients who have received concomitant PLAZO and cardiac glycosides. However, some of the macrolide antibiotics have been reported to impair the metabolism of digoxin (in the gout) in some patients. Therefore, in patients receiving concomitant PLAZO and digoxin the possibility of raised digoxin levels should be borne in mind.

Erogot derivatives
Because of the theoretical possibility of ergotism, PLAZO and ergot derivatives should not be co-administered.

Warfarin
In a pharmacokinetics interaction study, PLAZO did not alter the anticoagulant effect of a single 15 mg of warfarin administered in healthy volunteers. PLAZO and warfarin may be co-administered, but monitoring of the prothrombin time should be continued as routinely performed.

Side-effects
PLAZO 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 of gastrointestinal origin with nausea, abdominal discomfort (pain/cramps), vomiting, flatulence, diarrhoea and loose stools being occasionally observed. Allergic reactions such as rash have occurred and there have also been rare reports of serious hypersensitivity reactions. Reversible elevations in liver transaminases have been seen with frequency similar to the comparative macrolides and penicillins used in clinical trials. Transient mild reductions in neutrophil counts have occasionally been observed in clinical trials, although a causal relationship to PLAZO has not been established.

Over dosage
There is no data on over dosage with PLAZO. Typical symptoms of over dosage with macrolide antibiotics including hearing loss, severe nausea, vomiting and diarrhoea. Gastric lavage and general supportive measures are indicated.

Direction for preparation
Prepare suspension according to the instructions given on the label.
Reconstituted suspension may be use for 10 days.

Storage
Store below 30°C in a day place, protect from light.
Keep bottle tightly closed.
To be dispensed on the prescription of a registered medical practitioner only.
keep out of the reach of children.

Presentation
PLAZO Tablets 250 mg are supplied in blister pack of 1 x 6's
PLAZO Tablets 500 mg are supplied in blister pack of 1 x 6's
PLAZO Oral suspension 200 mg / 5 ml; Powder for 15 ml suspension (after reconstituted) is supplied in bottle

Note: Plazo tablet contains lactose. نوٹ: پلازو ٹیبلیٹ میں لیکٹوز شامل ہے۔

D2B

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Colors
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