



RESQUE

(Azithromycin) USP

CAPSULES

TABLETS

DRY POWDER FOR SUSPENSION

DESCRIPTION

Azithromycin is an azalide antibiotic, a subclass of the macrolide class of antibiotics. Azithromycin acts by binding to the 50S ribosomal subunit of susceptible organisms and thus interferes with microbial protein synthesis. Following oral administration in humans, azithromycin is rapidly absorbed and widely distributed throughout the body; bioavailability is approximately 37%. However, kinetic studies have shown markedly higher azithromycin levels in tissues than in plasma or serum indicating that the drug is highly tissue bound and achieves high concentration within cells.

COMPOSITION

RESQUE CAPSULES

Each capsule contains:

Azithromycin as dihydrate (USP).....250mg

RESQUE TABLETS

Each film coated tablet contains:

Azithromycin as dihydrate (USP).....500mg

RESQUE DRY POWDER FOR SUSPENSION

Each 5ml reconstituted suspension contains:

Azithromycin as dihydrate (USP).....200mg

INDICATIONS

- Azithromycin is indicated in lower respiratory tract infections including bronchitis and pneumonia.
- In upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis.
- In otitis media.
- In skin and soft-tissue infections (caused by susceptible organisms).
- In urinary tract infections.
- In sexually transmitted diseases in men and women.
- In non-gonococcal urethritis and cervicitis due to Chlamydia trachomatis.
- And in mild to moderate typhoid fever caused by multi-drug resistant strains.

DOSAGE & ADMINISTRATION

Since food decreases the absorption of azithromycin therefore it should be taken at least 1 hour before or 2 hours after meal.

ADULTS

- For lower respiratory tract infections including bronchitis and pneumonia, upper respiratory tract infections including sinusitis

and pharyngitis/tonsillitis, otitis media and skin and soft tissue infections, the total dose is 1.5g, given as 500mg once daily for 3 days. An alternative to this dosage schedule is 500mg once daily on day 1, followed by 250mg once daily for next 4 days.

- For sexually transmitted diseases caused by Chlamydia trachomatis, the dose is 1g given as a single dose. Alternatively, 500mg once daily on day 1, followed by 250mg once daily for next 2 days may also be given.

USE IN THE ELDERLY

Normal adult dosage is recommended.

CHILDREN

The dose in children over 6 months of age is 10mg/kg body weight once daily for 3 days. Alternatively, 10mg/kg on day 1 followed by 5mg/kg for next 4 days is also recommended. There is no information on the use of Azithromycin in children under 6 months of age.

FOR CHILDREN

With body weight 15-25kg (3-7 years), the dose is 200mg once daily for 3 days. For body weight 26-35kg (8-11 years), the dose is 300mg once daily for 3 days. For body weight 36-45 kg (12-14 years), the dose is 400mg once daily for 3 days. For body weight over 45kg, normal adult dosage is recommended.

SIDE EFFECTS

Azithromycin is well tolerated with a low incidence of side-effects. The side-effects include nausea, vomiting, abdominal discomfort (pain/cramps), flatulence, diarrhoea, headache, dizziness and skin rashes and are reversible upon discontinuation of therapy. Reversible elevations in liver transaminases have been observed occasionally. Transient mild reductions in neutrophil counts have occasionally been observed in clinical trials, although causal relationship to azithromycin has been established.

OVER-DOSAGE

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

CONTRA-INDICATIONS

Azithromycin is contra-indicated in patients with a known hypersensitivity to azithromycin or any of the macrolide antibiotics.

PRECAUTIONS & WARNINGS

Azithromycin absorption is reduced by 50% in the presence of food in stomach. It should therefore be taken 1 hour before or 2 hours after meal. Avoid concomitant administration with terfenadine or astemizole. Precaution should be taken in patients with hepatic impairment and more severe renal impairment. Azithromycin should

be used during pregnancy and lactation only if adequate alternatives are not available.

DRUG INTERACTIONS

ANTACIDS: Peak serum levels (but not the total extent of absorption) are reduced by Aluminium and magnesium containing antacids. Azithromycin should therefore be taken at least 1 hour before or 2 hours after these antacids.

ERGOT DERIVATIVES: Because of the theoretical possibility of ergotism, concomitant administration of ergot derivatives and azithromycin should be avoided.

DIGOXIN & CYCLOSPORIN: Macrolides are known to increase the plasma concentrations of digoxin & cyclosporin and so caution should be exercised when coadministration is necessary.

ANTI-HISTAMINES: A potentially life threatening interaction between erythromycin and terfenadine has been reported. Although such an interaction with azithromycin is not established yet, so it is wise to avoid concomitant use of azithromycin and terfenadine. There have been no pharmacokinetic drug interactions of azithromycin of warfarin, theophylline, carbamazepine, methylprednisolone and cimetidine. In clinical trials, around 45% patients receiving azithromycin also received other drugs concomitantly; e.g., bronchodilators, analgesics, corticosteroids, diuretics, anxiolytics and antiarthritic drugs. No drug interaction problems were encountered.

DIRECTIONS FOR RECONSTITUTION OF SUSPENSION

RESQUE DRY POWDER FOR SUSPENSION 200mg/5ml (5ml)

Tap the bottle several times to loosen powder prior to reconstitution. Add a small quantity of previously boiled cool water to the powder in bottle and shake well, then add water upto the lower mark on bottle and shake well. Use reconstituted suspension within 10 days.

RESQUE DRY POWDER FOR SUSPENSION 200mg/5ml (15ml)

Tap the bottle several times to loosen powder prior to reconstitution. Add a small quantity of previously boiled cool water to the powder in bottle and shake well, then add water upto the upper mark on bottle and shake well. Use reconstituted suspension within 10 days.

RESQUE DRY POWDER FOR SUSPENSION 200mg/5ml (30ml)

Tap the bottle several times to loosen powder prior to reconstitution. Add 10ml of previously boiled cool water using enclosed cup and shake well. Again add 10ml of previously boiled cool water in it and shake well to make 30ml suspension. Use reconstituted suspension within 10 days.

INSTRUCTIONS

Store at 15-30°C. Protect from heat, light & moisture. Keep all

medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only. Physician sample (5ml) is not for sale.

PRESENTATION

RESQUE capsules Alu-Alu pack of 6 capsules

RESQUE tablets Alu-Alu pack of 6 film coated tablets

RESQUE dry powder for reconstituted suspension of 15ml and 30ml.

ریسکیو

(آڈیٹور و مائیکسین) برائے نی

کپسول / گولیاں / ڈرائی پاؤڈر برائے سسپینشن

5 ملی لیٹر سسپینشن تیار کرنے کا طریقہ: (200mg/5ml)

سسپینشن بنانے کے لیے بوتل کو اچھی طرح ہلائیں تاکہ تمام پاؤڈر یکجا ہو جائے۔ اب بوتل میں تھوڑا سا پہلے سے اُبلایا ہوا ٹھنڈا پانی شامل کریں اور ڈھکن لگا کر اچھی طرح ہلائیں۔ اب بوتل پر بننے والے نشان کے مطابق اُبلایا ہوا ٹھنڈا پانی شامل کریں اور ڈھکن لگا کر اچھی طرح ہلائیں۔ تیار شدہ دوا 10 دن کے اندر استعمال کریں۔

15 ملی لیٹر سسپینشن تیار کرنے کا طریقہ: (200mg/5ml)

سسپینشن بنانے کے لیے بوتل کو اچھی طرح ہلائیں تاکہ تمام پاؤڈر یکجا ہو جائے۔ اب بوتل میں تھوڑا سا پہلے سے اُبلایا ہوا ٹھنڈا پانی شامل کریں اور ڈھکن لگا کر اچھی طرح ہلائیں۔ اب بوتل پر بننے والے نشان کے مطابق اُبلایا ہوا ٹھنڈا پانی شامل کریں اور ڈھکن لگا کر اچھی طرح ہلائیں۔ تیار شدہ دوا 10 دن کے اندر استعمال کریں۔

30 ملی لیٹر سسپینشن تیار کرنے کا طریقہ: (200mg/5ml)

سسپینشن بنانے کے لیے بوتل کو اچھی طرح ہلائیں تاکہ تمام پاؤڈر یکجا ہو جائے۔ اب ڈبے میں موجود کپ سے ناپ کر 10 ملی لیٹر پہلے سے اُبلایا ہوا ٹھنڈا پانی شامل کریں اور اچھی طرح ہلائیں۔ پھر مزید 10 ملی لیٹر پہلے سے اُبلایا ہوا ٹھنڈا پانی شامل کریں اور ڈھکن لگا کر اچھی طرح ہلائیں تاکہ 30 ملی لیٹر سسپینشن تیار ہو جائے۔ تیار شدہ دوا 10 دن کے اندر استعمال کریں۔

خوراک: دوا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: دوا کو 15-30° سینٹی گریڈ پر رکھیں۔ گرمی، روشنی اور نمی سے محفوظ رکھیں۔

تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔



Manufactured by:
STANDPHARM PAKISTAN (PVT) LTD.
20 Km Ferozpur Road Lahore, Pakistan.

0370-00