Servaz

(Azithromycin)

سَروِیز

(ایزتھرومائیسن)

COMPOSITION:

SERVAZ tablet 500mg
Each film coated tablet contains:
Azithromycin as dihydrate ……. 500 mg

SERVAZ tablet 250mg
Each film coated tablet contains:
Azithromycin as dihydrate ……. 250 mg

SERVAZ 200mg/5ml suspension
Each 5 ml suspension contains:
Azithromycin as dihydrate ..... 200 mg

SERVAZ capsule 250mg
Each capsule contains:
Azithromycin as dihydrate ..... 250 mg

SERVAZ capsule 500mg
Each capsule contains:
Azithromycin as dihydrate ..... 500 mg

Properties:

Azithromycin is an azalide, derived from the macrolide class of antibiotics. **SERVAZ** 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 Chlamydia trachomatis. **SERVAZ** also demonstrates in vitro activity against Legionella pneumophila; Mycoplasma pneumoniae and hominis; Campylobacter sp: Toxoplasma gondii and Treponema pallidum.

Pharmacokineties:

Following oral administration in humans, **SERVAZ** 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 **SERVAZ** 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:

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

Dosage and Administration:

SERVAZ tablet / capsule should be administered as a single dose.
SERVAZ tablet / capsule can be taken with or without food.
SERVAZ suspension should be given at least I 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.

Use in children:

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

Dosage Schedule:

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

* One TSF = 5 ml measures provided.
For body weight over 45 kg; normal adult dosage is recommended.

Contra-Indications:

SERVAZ is contraindicated 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.

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 Azithromycin 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 **SERVAZ** usage in patients with more severe renal impairment. thus caution should be exercised in using **SERVAZ** in these patients.

Use in hepatic impairment:

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

Use during pregnancy and lactation:

Pregnancy:

Animal reproduction studies have demonstrated that Azithromycin 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, **SERVAZ** should be used during pregnancy only if adequate alternatives are not available

Lactation:

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

Drug interactions:

Antacids:

In patients receiving **SERVAZ** and antacids, **SERVAZ** 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 Azithromycin and cyclosporin, caution should be exercised before co-administration of these two drugs. If co-administration is necessary, cyclosporin levels should he monitored and the dose adjusted accordingly.

Digoxin:
No interactions have been reported in patients who have received concomitant **SERVAZ** 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 **SERVAZ** and digoxin, the possibility of raised digoxin levels should be borne in mind.

Ergot derivatives:
Because of the theoretical possibility of ergotism, **SERVAZ** and ergot derivatives should not be co-administered.

Warfarin:

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

Side-effects:
SERVAZ 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 **SERVAZ** has not been established.

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

Storage conditions:
Protect from heat, light & moisture. **SERVAZ** tablets & suspension should be stored below 30°C.
The reconstituted suspension should be used within 10 days.

Direction for Preparation (SERVAZ Suspension):
Add one cup of boiled and cooled water to the dry powder using the cup inside and shake well to make 15 ml suspension.

Presentation:
SERVAZ 500mg Tablets are supplied in blister pack of 1 x 6's
SERVAZ 250mg Tablets are supplied in blister pack of 1 x 6's
SERVAZ 200mg/5ml suspension are supplied is 15 ml oral suspension
SERVAZ 250mg capsule are supplied in blister pack of 1 x10's
SERVAZ 500mg capsule are supplied in blister pack of 1 x 6's

Warnings:
Dosage: As directed by the physician.
Store below 30°C in a dry place, protect from light.
Keep bottle tightly closed.
Keep out of the reach of children.
shake well before use

Manufactured by:
Kaizen Pharmaceuticals (Pvt.) Ltd
E-127-129, North Western Industrial Zone
Bin Qasim, Karachi-75020, Pakistan.

ART No. 022/4

سَروِیز (SERVAZ)

(ایزتھروما ئسین)

ایزتھروما ئسین(سَروِیز - SERVAZ) ایک ایسا کیمیائی جُز ہے جو بہت سی اقسام کے جراثیم کے خلاف موثر ہے۔

سَروِیز (SERVAZ) مندرجہ ذیل انفیکشنز میں استعمال کی جاسکتی ہے۔

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

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

خوراک اور طریقہ استعمال :

سَروِیز (SERVAZ) کی خوراک مریض کی عمر اور وزن کے مطابق طے کی جاتی ہے۔

عمومی خوراک :

بالغ افراد میں سَروِیز (SERVAZ) 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 :

سَروِیز (SERVAZ) گولیاں کھانے کے ساتھ یا کھانا کھائے بغیر بھی لی جاسکتی ہیں۔

غیر ضروری علامات :

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

ممنوعات / احتیاط :

ایسے مریض جو ایزتھروما ئسین یا کسی بھی Macrolide antibiotics سے حساسیت رکھتے ہوں
سَروِیز (SERVAZ) کا استعمال نہ کریں۔
جگر کی بیماریوں میں مبتلا مریضوں کو ایزتھروما ئسین استعمال نہیں کرنی چاہیئے۔
حاملہ اور دودھ پلانے والی خواتین سَروِیز (SERVAZ) اپنے ڈاکٹر کے مشورے کے مطابق استعمال کریں۔
سَروِیز (SERVAZ) کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ ہر استعمال سے پہلے اچھی طرح ہلائیں۔
خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔