

کپسولز

سائیکلوسن®

سائیکلوسیرین یو۔ ایس۔ پی ۲۵۰ ملی گرام

وسیع العمل اینٹی بائیوٹک

خوراک:

بڑوں کیلئے:

سائیکلوسیرین کی بالائی خوراک ۱۵ سے ۲۰ ملی گرام فی کلو گرام بلحاظ وزن اور عمومی خوراک ۲ سے ۳ کپسولز روزانہ ہے۔

بچوں کیلئے:

بچوں میں سائیکلوسیرین کا استعمال محدود ہے۔ تاہم بچوں میں ابتدائی خوراک ۱۰ ملی گرام فی کلو گرام بلحاظ وزن تجویز کی جاسکتی ہے۔

ہدایات:

* دوا کو ٹھنڈی (۲۵ سینٹی گریڈ) درجہ حرارت سے کم (اور خشک جگہ) پر رکھیں۔

* دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔

* تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

* صرف رجسٹرڈ میڈیکل ڈاکٹر کی ہدایات کے مطابق اور زیر نگرانی استعمال کی جائے۔

پیشکش:

سائیکلون ۲۵۰ ملی گرام کپسولز (۱۰x۱) بلسٹر پیک میں دستیاب ہیں۔



Manufactured by:

Schazoo Zaka (Pvt) Ltd.

Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhpura, Pakistan.

CYCLOSEN® Cycloserine 250 mg

Capsules

COMPOSITION:

Each capsule contains;
Cycloserine U.S.P.250 mg.

CLINICAL PHARMACOLOGY:

MECHANISM OF ACTION:

Cycloserine is an effective drug against Mycobacterium tuberculosis that is resistant to first line anti-TB drugs. Cycloserine can be bactericidal or bacteriostatic depending upon the dose administered. It is a structural analog of the amino acid D-alanine, which is important in the synthesis of peptidoglycan, the substance that gives cell walls, their rigid mechanical stability. Cycloserine competes with D-alanine for two enzymes, L-alanine racemase and D-alanine synthetase, both of which are involved in the incorporation of D-alanine into bacterial cell walls. Cycloserine inhibits both enzymes and peptidoglycan synthesis, resulting in a weak cell wall and eventually cell lysis. Cycloserine has an exceptional effectiveness in inhibiting Mycobacterium tuberculosis.

PHARMACOKINETICS:

After an oral administration, Cycloserine is readily and almost completely absorbed from the gastro-intestinal tract. Peak plasma concentrations of 10 µg per ml have been obtained 3 to 4 hours after a dose of 250 mg rising to 20-30 µg per ml on repeating the dose every 12 hours. The plasma half life is about 10 hours and is prolonged in patients with renal impairment. The cycloserine is widely distributed in body tissues and fluids including the lungs, acidic fluids, pleural fluid, and synovial fluid in concentrations similar to those in the serum. It also distributes into bile, sputum, and lymph tissues. Distribution into the CSF (Cerebro-spinal fluid) is approximately 50-80 % of the current plasma concentration. Cycloserine readily crosses the placenta and is distributed into the amniotic fluid and breast milk. About 60 – 70 % of an oral dose is renally excreted unchanged, with a plasma half-life of approximately 10 hours. Both plasma concentrations and the half-life of cycloserine are increased in patients with renal impairment, and dosage adjustments are required in these patients.

INDICATIONS & USAGE:

- Cycloserine is a second-line, broad spectrum antibiotic used in the treatment of;
- Active pulmonary and Extrapulmonary tuberculosis when the causative organisms are susceptible to this drug and when treatment with the primary medications (streptomycin, isoniazid, rifampicin and ethambutol) has proved inadequate.
 - Like all antituberculosis drugs, cycloserine should be administered in conjunction with other effective anti-TB chemotherapy and not as the sole therapeutic agent.

DOSAGE & ADMINISTRATION:**WHO RECOMMENDATIONS:**

Cycloserine is a bacteriostatic drug at the usual dosage. The drug is given orally in capsules or tablets form containing; 250 mg of cycloserine.

The maximum daily dose is 15-20 mg/kg body weight; the usual dose is 2-3 capsules (500-750 mg) of cycloserine per day. Few patients tolerate more than 750 mg daily, and in the continuation phase more than 500 mg daily. The daily dose can be given in two intakes:

Cycloserine: 250mg, in the morning, and 500 mg 12 hours later.

Second line regimen for the treatment of MDR Tuberculosis

Resistance to	Initial phase		Continuation phase	
	Drugs	Minimum duration in months	Drugs	Duration in months
Isoniazid, Rifampicin, Streptomycin, and Ethambutol.	1.Aminoglycoside	3	1.Ethionamide	18
	2.Ethionamide	3	2.Ofloxacin	18
	3.Pyrazinamide	3	3.Cycloserine	18
	4.Ofloxacin	3		
	5.Cycloserine	3		

CHILDREN:

The use of cycloserine in children is limited. However, an initial pediatric dose of 10 mg/kg body weight has been suggested.

MISSED DOSE:

If a dose of cycloserine is missed, take it as soon as possible. It helps to keep a constant amount of medicine in blood or urine. However, if it is almost time for next dose, skip the missed dose and go back to regular dosing schedule. Do not take double dose.

CONTRA-INDICATIONS:

Cycloserine is contra-indicated in patients with;

- Hypersensitivity to cycloserine,
- Epilepsy,
- Depression, severe anxiety, or psychosis,
- Severe renal insufficiency,
- Excessive concurrent use of alcohol.

PRECAUTIONS & WARNINGS:

Cycloserine has a low therapeutic index, and dosage should be adjusted according to the plasma concentrations which should be monitored at least weekly in patients with renal impairment, for those taking dose greater than 500 mg daily, and also in patients showing signs of neurological toxicity. Plasma concentrations should be maintained below 30 µg per ml. Patients with renal impairment require lower doses.

Before initiating treatment with cyclosen capsules, cultures should be taken and the organism's susceptibility to the drug should be established. In tuberculosis, the organism's susceptibility to the other antituberculosis agents in the regimen should also be demonstrated.

Cycloserine should be discontinued or the dose reduced if allergic dermatitis or symptoms of CNS toxicity develop.

DRUG INTERACTIONS:

Patients receiving cycloserine with alcohol are at increased risk of convulsions. Neurotoxic effects may be potentiated by concurrent administration of cycloserine and ethionamide and increased CNS toxicity, such as dizziness and drowsiness, may occur in patients receiving cycloserine and isoniazid.

USE IN PREGNANCY:

Cycloserine should be used in pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

NURSING MOTHERS:

Because of the potential for serious adverse reactions in nursing infants from cycloserine, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

SIDE EFFECTS:

The adverse effects of cycloserine involve the anxiety, confusion, depression, psychoses, irritability, and paranoia. Vertigo, headache, drowsiness, tremor, hyperreflexia, allergy, skin rash, increased serum transaminase especially in patients with pre-existing liver disease and convulsion may also occur. Neurological reactions are dose related and may be reduced by keeping the plasma concentration below 30 µg per ml.

OVERDOSAGE:

Acute toxicity from cycloserine can occur if more than 1 g is ingested by an adult. Chronic toxicity from cycloserine is dose related and can occur if more than 500 mg is administered daily. Patients with renal impairment will accumulate cycloserine and may develop toxicity if the dosing regimen is not modified. Patients with severe renal impairment should not take this drug. The central nervous system is the most common organ system involved with toxicity.

Treatment:

The following precautions should be provided, if over dosage of cycloserine have been encountered.

Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patients vital signs, blood gases, serum electrolytes, etc. absorption of the drug from the gastrointestinal tract may be decreased by giving activated charcoal, which, in many cases, is more effective than emesis or lavage, consider charcoal instead of or in addition to gastric emptying. Repeated doses of charcoal over time may hasten elimination of some drugs that have been absorbed. Safeguard the patients airway when employing gastric emptying or charcoal.

In adults, many of the neurotoxic effects of cycloserine can be treated and prevented with the administration of 200 to 300 mg of pyridoxine daily.

STORAGE CONDITIONS:

- * Store in a cool and dry place below 25°C.
- * Protect from heat, light and moisture.
- * Keep all medicines out of the reach of children.

PACKING:

Cyclosen 250 mg capsules are available in (1x10) blister pack.

To be used strictly on the prescription and under supervision of a registered medical practitioner .