گولياں



# نطلائن علاج مح

ں کے لیے یومیہ: ، کلوگرام اور اس سے ذائد وزن کے بالغان کے لیے: ۱۵ تا ۲۰ مای کرام فی کلوگرام ملجا ظورزن روزلنز (اگرام تک) ۵ کلوگرام سے کم دزین کے بالغان کے لیے : ۱۵،۲۰ فی گرام فی کلوگرام بلجاظ وزن روزاره (۵۰ فی گرام تک) العوم برد سے ١٧ گھنٹے کے بعد کھانے کے ساتھ یا کھانے کے بعد اِستعال کریں۔ بچتون کے لیے یہ هیسه: ۱۵ تا ۲۶ مل گرام فی کلوگرام بلحاظ وزن روزلد(۵۰ علی گرام تک) یا ڈاکٹر کی ہدلیات کے مطابق \* بچگرمنا فتر ہونے کا امکان ہے اِس لیے عگر کی بیار این اِس کا استعال ممثوع ہے۔ \* دورانِ عمل دواکے استعال میں اِستیاط طروری ہے تیونکھ اس دوران اس کا استعمال \* دواکو ٹھنڈی اور شکا جگر ہر رکھیں۔ \* دواکو گری، رقبی اور ٹی سے مفوظ رکھیں۔ \* دواصر فی ڈاکٹر کی ہدایات کے شطیابی استعال کریں۔ \* دواصر فی داکٹر کی ہدایات کے شطیابی استعال کریں۔ المنظم من المنظم من المنظم ال ETHOMI

Ethionamide U.S.P. 250 mg

## FOR 2ND LINE TREATMENT IN TUBERCULOSIS

#### COMPOSITION:

Each film coated Tablet contains: Ethionamide U.S.P. ...... 250 mg.

**CLINICAL PHARMACOLOGY:** Ethionamide may be bacteriostatic or bactericidal in action, depending on the concentration of the drug attained at the site of infection & the susceptibility of the infect-ing organism Ethionamide is a highly specific agent & is active against organisms of genus Mycobacterium.

Ethionamide is active in vitro & in vivo against M. tuberculosis, M. bovis, M. Kansasii and some strains of M. avium & M. intracellular. The drug is also active against M. leprae.

After administration of single oral dose 80% of Ethionamide is rapidly absorbed from the GI tract. Following a single 1gm oral dose in adults, peak plasma concentrations of Ethionamide averaging 20 $\mu$ g/ml are attained within 3 hours plasma concentrations of the drug average 3 $\mu$ g/ml at 9 hours and less than 1 $\mu$ g/ml at 24 hours.

Ethionamide is widely distributed into body tissues & fluids; concentrations in plasma and various organs are approximately equal. The drug is 10% bound to plasma proteins. The concentration of ethionamide in CSF is reported to be equal to concurrent plasma concentrations of the drug in patients with normal or inflammed meninges.

In a study in children with tuberculous meningitis, peak concentrations of ethionamide in CSF generally occurred

 $1.5\ to\ 2.5\ hours$  after oral doses of  $15\ or\ 20\ mg/kg$  but showed considerable interindividual variation. Ethionamide readily crosses the placenta. It is not known if ethionamide is distributed into milk.

Schazoo Zaka (Pvt) Ltd. Kalalwala, 20-Km Lahore-Jaranwala Road, Distt: Sheikhupura, Pakistan.

The plasma half-life of ethionamide is approximately 3 hours. Ethionamide is extensively metabolized to active and inactive metabolites, probably in the liver. The major active metabolite is the sulfoxide, which may be converted back to ethionamide in vivo. Within 24 hours, 1-5% of an oral dose of ethionamide is excreted in urine as active drug & metabolites; the remainder is excreted in urine as inactive metabolites. metabolites.

### SIDE EFFECTS:

- GI (Gastrointestinal) disturbances are the most frequent adverse effects of ethionamide. Adverse GI effects of the drug include nausea, vomiting, abdominal pain, diarr-hoea, excessive salivation, metallic taste, anorexia & wt. loss. Adverse GI effects appear to be dose related & may be minimized by decreasing dosage or changing the time of drug administration.
- Mental depression, restlessness, drowsiness, dizziness, headache, postural hypotension, and asthenia occur occasionally with ethionamide. Rarely, peripheral neuritis, paresthesia, seizures, tremors, a pellagra like syndrome, hallucinations, diplopia, optic neuritis, blurred vision, and olfactory disturbances have been reported.
- Transient increases in serum bilirubin, AST (SGOT), and ALT (SGPT) concentrations have been reported in patients receiving ethionamide. Hepatitis (with or without jaundice) has also been reported, especially in patients with diabetes mellitus. Hepatotoxicity generally is reversible on discontinuation of the drug.

#### INDICATIONS:

- For the second line treatment of tuberculosis. Failure after adequate treatment with primary drugs (Isoniazid, Streptomycin, Rifampicin, Pyrazinamide & Ethambutol HCl) in any form of active tuberculosis.
- In Patient with multidrug resistance ethionamide should only be given with other effective antituberculous agents.
- Ethionamide is also used in conjunction with other anti-infective agents in the treatment of other mycobacterial

### **CONTRA-INDICATIONS:**

- Ethomid is contra indicated in patients with severe hepatic impairment and in patients who are hypersensitive to the drug.
- Optimum dosage of **Ethomid** in children has not been established, this should not preclude the use of the drug when it is considered necessary in antituberculosis therapy.
- Safe use of **Ethomid** during pregnancy has not been established. The drug has caused teratogenic effects in animals when administered in high doses. **Ethomid** should not be used in women who are or may become pregnant unless the potential benefits outweigh the possible risks to the fetus.

#### DOSAGE & ADMINISTRATION:

In the treatment of clinical tuberculosis and other mycobacterial diseases, Ethionamide should not be given alone. During the treatment pyridoxine (vitamin B-6) supplements should be taken with Ethionamide.

#### For Adults:

The usual adult dosage of **Ethomid** for the treatment of

the usual adult dosage of **Etholia** of the treatment of tuberculosis and other mycobacterial diseases is 15 – 20 mg/kg body weight (upto 1gm) daily.

Patients body weight more than 50 kg = 1 gm /day.

Patients body weight less than 50 kg = 750 mg /day.

Usually every 8 to 12 hours, with or after meals.

#### For Children:

Pediatric dosage of 15-20 mg/kg body weight (up to 750 mg) daily has been recommended.
Or as advised by the Chest Physician.

#### CAUTION:

IF YOU FORGET A DOSE:

Take as soon as you remember up to 2 hours late. If more than 2 hours. Wait for next scheduled dose. Don't double this dose.

#### STORAGE:

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

Ethomid film coated tablets are available in (3x10) blister pack tablets.