

**PACKAGE LEAFLET**

**PACKAGE LEAFLET: INFORMATION FOR THE USER****Ethionamide 250 mg Tablets**  
ethionamide**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

**In this leaflet:**

1. What Ethionamide 250 mg Tablets is and what it is used for
2. Before you take Ethionamide 250 mg Tablets
3. How to take Ethionamide 250 mg Tablets
4. Possible side effects
5. How to store Ethionamide 250 mg Tablets
6. Further information

**1. WHAT ETHIONAMIDE TABLETS IS AND WHAT IT IS USED FOR**

Ethionamide is used in combination with other antituberculosis agents for the treatment of all forms of tuberculosis caused by *Mycobacterium tuberculosis*.

Ethionamide is only used as a second line antimycobacterial drug when resistance to or toxicity from first-line drugs has developed.

**2. BEFORE YOU TAKE ETHIONAMIDE TABLETS****Do not take Ethionamide Tablets:**

- if you are hypersensitive (allergic) to ethionamide or any of the other ingredients of Ethionamide Tablets (see section 6, What Ethionamide Tablets contains),
- if you have severe liver disease.

**Take special care with Ethionamide Tablets:**

Take Ethionamide Tablets always together with other antituberculosis drugs, that your doctor or health care provider prescribes you.

If you develop clinical symptoms suggesting an injury of the liver, such as loss of appetite, nausea, jaundice (yellowing of the skin and eye white), dark urine, discoloured stools, pain and tenderness in the upper right abdomen, tell your doctor immediately.

If you experience rash or fever (possible signs of an allergic reaction), tell your doctor or health care provider immediately.

Your doctor or health care provider will regularly monitor your blood sugar, your thyroid function and your visual acuity throughout therapy with Ethionamide because ethionamide may lead to alterations (see "Undesirable effects").

Your doctor may prescribe a certain vitamin, called pyridoxine, for you to be taken concomitantly with ethionamide. This medicine may reduce the risk of developing nerve damage.

It is important that your doctor or health care provider knows about all your symptoms even when you think they are not related to tuberculosis infection.

### **Taking other medicines**

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. These may affect the action of Ethionamide Tablets, or Ethionamide Tablets may affect their action.

Ethionamide may interact with isoniazid and rifampicin and may make side effects worse:

Ethionamide Tablets should not be taken with large amounts of alcohol.

### **Taking Ethionamide Tablets with food and drink**

Ethionamide Tablets may be taken with or without food. Intake with food may reduce gastrointestinal side effects.

### **Pregnancy and breast-feeding**

You should avoid becoming pregnant while on treatment with Ethionamide Tablets. If you become pregnant, or are planning to become pregnant, you must contact your doctor or health care provider to discuss the potential benefits and risks of your tuberculosis therapy to you and your child.

It is not known whether ethionamide is excreted into human milk. If continuation of breast-feeding during ethionamide treatment is deemed necessary, your baby should be closely monitored for side effects of ethionamide (see section 4.8).

### **Driving and using machines**

Ethionamide may cause side effects such as drowsiness or headache, that can impair your ability to drive and to use machines.

## **3. HOW TO TAKE ETHIONAMIDE TABLETS**

Always take Ethionamide Tablets exactly as your doctor or health care provider told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

Your doctor will assign the dose of Ethionamide Tablets appropriate for you. The following information includes only the average doses of this medicine. If your prescribed dose is different, do not change it unless your doctor or health care provider tells you to do so.

For adults the usual daily dose is two to four tablets (500 mg to 1 g daily), depending on body weight and tolerance. The daily dose can be taken either at a single occasion or split up in two doses over the day to improve tolerability. Ethionamide Tablets may be taken with or without food. Intake with food may improve gastrointestinal tolerability.

Children:

For children the dose must be determined by the doctor that prescribes the drug. Doses of 10-20 mg/kg of body weight per day have been recommended. The dose can be taken either at a single occasion or split up in two doses over the day to improve tolerability.

If you have severe liver disease you must not take ethionamide (see “Do not take {product name}”). No dose adjustment is necessary if you have a kidney disease.

### **If you take more Ethionamide Tablets than you should**

If you have taken too many tablets or if someone accidentally swallows some, there is no immediate danger. However, you should contact your doctor, health care provider or the nearest hospital emergency department for further advice.

**If you forget to take Ethionamide Tablets**

If you accidentally miss a dose and notice within 6 hours take the missed dose as soon as possible. Take the next regular dose as scheduled. If you notice later, then simply take your normal dose when the next one is due. Do not take a double dose to make up for forgotten individual doses.

**If you stop taking Ethionamide Tablets**

Keep taking the medicine for as long as your doctor has told you, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured.

You should not stop treatment unless your doctor or health care provider tells you to.

If you have any further questions on the use of this product, ask your doctor or health care provider or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Ethionamide Tablets can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by Ethionamide Tablets, or those caused by any other medicines you may be taking at the same time. For this reason, it is important that you inform your doctor or health care provider of any change in your health.

The *most commonly* reported side effects (greater than 1 in 10 patients treated) are stomach discomfort, abdominal pain, loss of appetite, vomiting, diarrhoea, nausea. The frequency depends on the dose and duration of therapy.

Furthermore, increased serum transaminases have been reported very commonly.

Other *common* side effects (greater than 1 in every 100 patients treated) are headache, dizziness, drowsiness, general weakness, feeling of pins and needles (paraesthesia), inflammation of the liver (hepatitis) and yellowing of the skin.

The following side effects have been reported in patients treated with ethionamide. However, frequency estimates for these effects are not available:

Decrease of platelets (blood cells important for blood clotting), metallic taste and sulphurous belching, increased salivation, taste disorders, a so called Pellagra-like syndrome (a condition presenting with diarrhoea, skin inflammation and impaired brain function, caused by a lack of niacin, a certain vitamin), thyroid underfunction, raised sugar in the blood, psychotic reactions (hallucinations, abnormal thinking, personality changes), low blood pressure (especially after standing up), altered brain function and/or structure (encephalopathy), tingling in the limbs, altered sense of smell, rash (red, raised or itchy), urticaria, acne, sensitivity to light (photosensitivity), inflammation of mucous lining (cheeks, gums, tongue, lips, throat), hair loss, red or purple discolouration on the skin (purpura), breast enlargement in male patients, menstrual disturbance, impotence, visual disturbance (blurred or double vision, complete or partial loss of vision), damage to the ear (e.g. dizziness, hearing loss, tinnitus), rash and fever.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or health care provider or pharmacist as soon as possible.

**5. HOW TO STORE ETHIONAMIDE TABLETS**

Keep out of the reach and sight of children.

Do not store above 30°C, protect from light.

Do not use Ethionamide Tablets after the expiry date which is stated on the <label,, carton,, jar> after expiry date. The expiry date refers to the last day of that month.

Do not use Ethionamide Tablets if you notice discolouration or swelling of tablets.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

## 6. FURTHER INFORMATION

### What Ethionamide Tablets contains

- The active ingredient is ethionamide.
- The other ingredients are Maize Starch, Gelatin, Sodium Starch Glycolate, Colloidal Anhydrous Silica, Gum Acacia, Purified Talc, Magnesium Stearate, Povidone, Hypromellose, Titanium Dioxide, Color Quinoline Yellow Supra, Diethyl Phthalate.

### What Ethionamide Tablets looks like and contents of the pack

Ethionamide Tablets are yellow circular, deep biconvex film coated tablets with plain surface on both sides and available as Aluminium/Aluminium Strip pack of 10 tablets, such 9 or 10 blisters per box or as bulk pack (packed in polybag (LDPE), placed inside PET/Al/LDPE triple laminated pouch and kept in HDPE Jar) with 100 tablets.

The tablets should not be divided.

### Supplier and Manufacturer

Macleods Pharmaceuticals Limited,  
Andheri East,  
Mumbai,  
India  
Phone:: +91 22 6676 2800  
Fax: +91 22 2821 6599  
Email: exports@macleodspharma.com

Oxalis Labs  
Village Theda  
P.O. Lodhimajra, Baddi,  
Dist.: Solan, Himachal Pradesh,  
India.  
Tel: +91-1-795 661400  
Fax: +91-1-795 661452

For any information about this medicinal product, please contact the local representative of the supplier:

<b>CAMBODIA</b>	<b>MYANMAR</b>	<b>MALAYSIA</b>
Curewel International Co ltd No.34, Street 208, Sangkat Boeung Raing Khan Daun Penh, Phnom Penh, Cambodia. Tel: 855 23 210422 Fax No : 855 23 210490	Shwe Kyar Gyi Co., Ltd No: (84), 12th Street, Lanmadan Township, Yangon, Myanmar Tel : 951- 212433 / 227028	Zulat Pharmacy SDN, BHDNo.23 & 23A Jalan Bandar 3, Taman Melawati, 53100 Kuala Lumpur, Malaysia. Tel : 603 41070620 / 41072061/ 4057451 Fax : 603 41071693

<b>PHILIPPINES</b> OEP PHILIPPINES, Inc, Unit 606 SEDCCO 1 Bldg. cor. Rada & Legaspi Sts, Legaspi Village, Makati City, Manila, Philippines Tel : 00632 8151209	<b>SRILANKA</b> Pettah Pharmacy Ltd 3/1 Leyden Bastian Rd York Arcade Bldg Colombo -01, Srilanka Tel: 94 112 431214 / 438591 Fax: 94 11 4736246	<b>THAILAND</b> ABC Pharmed (Thailand) Co. Ltd. 1848, Jaransanitwong Rd, SOI 65 Bangbamru, Bangplad, Bangkok, 10700 Thailand. Tel: 662 433 0246 9 Fax: 662 433 0248
<b>ETHIOPIA</b> General Chemicals & Trading Pvt. Ltd. Co,	<b>KENYA</b> Sai Pharmaceuticals Ltd. P.O.Box 66551 - Westlands	<b>TANZANIA</b> Tata Holdings (Tanzania Ltd.) Nyerere Road (Pugu Road)

P.O.Box 5620, Addis Ababa, Ethiopia. Fax: 002511 514979	00800, Nairobi, Kenya Tel : 00254 20 3753004/5/6 Fax : 00254 20 3752200	P.O.Box 31471 DAR ES SALAM, Tanzania. Tel : 00255744393633/ 255 22 28622589
<b>ZAMBIA</b> Prime Pharmaceuticals Limited Cusa House, 1st Floor,Cairo Road, P.O.Box 32072,Lusaka, ZAMBIA. Tel : 002601-222070 Fax :002601-293458	<b>ZIMBABWE</b> Medivision Zimbabwe (PTY LTD) 33 Craster Road Southern Harare Zimbabwe Tel: +263 42 53 445 Fax: +263 42 53 445	<b>UGANDA</b> NORVIK ENTERPRISES LTD., # 78/3, KAMPALA ROAD, (Opp.Sure House), Kampala, Uganda. Tel.: +256-41-346670 / 251067 Fax: +256-41-346680
<b>BELARUS</b> FE Medinter 164, F.Skoriny ave., 220141, Minsk, Belarus. Tel : +375 17 211 6292 Fax : +375 17 260 8533	<b>GEORGIA</b> MRG-Marketing and research Group Rep. Office Georgia 33-a Paliashvili st. 0071 Tbilisi, Georgia Tel : (+ 995 32) 23 01 06 Fax: (+ 995 32) 25 00 61	<b>KAZAKHSTAN</b> Avin Group of Companies 29/31 Radonezhskogo Sergiya Street, bld. 1 107120 Moscow, Russia. Tel/Fax: +7 495 777 19 60/ +7 495 777 19 61
<b>KYRGYZSTAN</b> INTERPHARMA 902 Vikram Towers, 16 Rajendra Place, New Delhi 110 008 Tel : 011-25869291/ 25863290/51538617	<b>RUSSIA</b> Advanced Trading Corporation Limited 27, Dmitrovskoye Shosse, Korpus:1,Office: 1028,29 and 30 Moscow,Russia-127550 Tel: + (7 095) 782 92 87 or 782 92 95 Fax: + (7 095) 782 92 29	<b>UKRAINE</b> Avin Group of Companies 29/31 Radonezhskogo Sergiya Street, bld. 1 107120 Moscow, Russia. Tel/Fax: +7 495 777 19 60/ +7 495 777 19 61
<b>THE NETHERLANDS</b> International Dispensary Association P.O.Box 37098, 1030 AB Amsterdam, The Netherlands. Tel : 003120-4033051 Fax : 03120-4031854	<b>DENMARK</b> Mission Pharma A/S.Vassingerodvej 9. DK-3540 Lyngø DENMARK. Tel : 45 48163200 Fax : 45 48163248	<b>COLOMBIA</b> VESALIUS PHARMA LTD A.CRA. 19 C NO. 86-14 OF. 602 EDIFICIO PARMA, BOGOTA, D.C. - COLOMBIA Fax : 571616 4773

**This leaflet was last approved in**

February 2008. Section 6 updated in November 2015.

Detailed information on this medicine is available on the World Health Organization (WHO) web site:  
<http://www.who.int/prequal/> .