

**SCHEDULING STATUS**

S4

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**ETHIONAMIDE MACLEODS 250 mg TABLETS** (film-coated tablets)

**READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TAKING ETHIONAMIDE MACLEODS 250 mg TABLETS**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ETHIONAMIDE MACLEODS 250 mg TABLETS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**WHAT ETHIONAMIDE MACLEODS 250 mg TABLETS CONTAINS**

Each film-coated tablet contains:

Ethionamide 250 mg

Sugar free

It also contains the following inactive ingredients: maize starch, gelatin (Type B), sodium starch glycolate (Type A), colloidal anhydrous silica, acacia, purified talc, magnesium stearate, povidone (PVP K-30), hypromellose (5 cps), titanium dioxide (CI no. 77891), colour quinoline yellow supra (CI no. 47005) and diethyl phthalate.

**WHAT ETHIONAMIDE MACLEODS 250 mg TABLETS IS USED FOR**

Tuberculosis (TB) treatment in combination with other medicine to treat tuberculosis when other first-line TB medicines do not help.

**BEFORE YOU TAKE ETHIONAMIDE MACLEODS 250 mg TABLETS**

**Do not take ETHIONAMIDE MACLEODS 250 mg TABLETS**

- If you are hypersensitive (allergic) to ethionamide or to any of the ingredients of **ETHIONAMIDE MACLEODS 250 mg TABLETS**.
- If you are hypersensitive (allergic) to isoniazid, pyrazinamide or niacin (other medicines used to treat tuberculosis), as you may also be sensitive to **ETHIONAMIDE MACLEODS 250 mg TABLETS**.
- If you have liver disease.
- If you are pregnant or breastfeeding your baby.

**Take special care with ETHIONAMIDE MACLEODS 250 mg TABLETS**

Inform your doctor if you have the following medical conditions before taking **ETHIONAMIDE MACLEODS 250 mg TABLETS**:

- Depression or other mental illness.
- Liver disease.
- Chronic alcoholism.
- Hypothyroidism (under functioning thyroid which leads to weight gain, lack of energy, thinning of hair, drying of skin and slowed mentality).
- Diabetes.
- Porphyria (**ETHIONAMIDE MACLEODS 250 mg TABLETS** should be avoided in porphyria).

**ETHIONAMIDE MACLEODS 250 mg TABLETS** will not be prescribed to you if you do not have normal liver function. Your doctor will monitor your liver function by performing blood tests before and during treatment (on a monthly basis) with **ETHIONAMIDE MACLEODS 250 mg TABLETS**. Your doctor will discontinue **ETHIONAMIDE MACLEODS 250 mg TABLETS** if your liver enzyme tests are abnormally high.

Your doctor may prescribe periodic eye examinations as **ETHIONAMIDE MACLEODS 250 mg TABLETS** may cause blurred vision, double vision and inflammation of the nerves of the eye causing loss of vision.

Your doctor may prescribe Vitamin B<sub>6</sub> (pyridoxine) or Vitamin B<sub>3</sub> (niacin) with **ETHIONAMIDE MACLEODS 250 mg TABLETS** to minimise adverse reactions such as dizziness, drowsiness or have neuropathy (damage to the nerves resulting in poor coordination, muscle weakness, pain in the fingers or toes, or numbness).

Diabetes may be difficult to manage. Your doctor will monitor your blood glucose levels on a regular basis.

**ETHIONAMIDE MACLEODS 250 mg TABLETS** may cause hypothyroidism or goiter (an abnormal swelling of the thyroid gland that causes a lump to form in the neck). Your doctor will monitor your thyroid function by doing regular blood tests.

In order to minimise gastrointestinal side-effects, **ETHIONAMIDE MACLEODS 250 mg TABLETS** may be taken at bedtime or in divided doses with meals. Your doctor may also prescribe medicine for nausea and vomiting.

#### **Taking ETHIONAMIDE MACLEODS 250 mg TABLETS with food and drink**

**ETHIONAMIDE MACLEODS 250 mg TABLETS** should preferably be taken with meals. Avoid alcohol. Excessive alcohol ingestion may cause a psychotic reaction (mental illness).

#### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **ETHIONAMIDE MACLEODS 250 mg TABLETS**.

**ETHIONAMIDE MACLEODS 250 mg TABLETS** should not be taken during pregnancy and breastfeeding.

#### **Driving and using machinery**

**ETHIONAMIDE MACLEODS 250 mg TABLETS** may cause dizziness and/or drowsiness. If you feel dizzy or drowsy while taking **ETHIONAMIDE MACLEODS 250 mg TABLETS** do not drive and do not use any tools or machines.

#### **Taking other medicines with ETHIONAMIDE MACLEODS 250 mg TABLETS**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

When you are taking **ETHIONAMIDE MACLEODS 250 mg TABLETS**, it is especially important to tell your doctor or healthcare professional if you are taking any other medicine and especially:

- thioacetazone – a medicine used in the treatment of tuberculosis (TB)
- cycloserin – a medicine used in the treatment of tuberculosis (TB)
- isoniazid– a medicine used in the treatment of tuberculosis (TB)
- terizidone – a medicine used in the treatment of tuberculosis (TB)
- rifampicin – a medicine used in the treatment of tuberculosis (TB)

#### **HOW TO TAKE ETHIONAMIDE MACLEODS 250 mg TABLETS**

Do not share medicines prescribed for you with any other person.

Always take **ETHIONAMIDE MACLEODS 250 mg TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **ETHIONAMIDE MACLEODS 250 mg TABLETS** is too strong or too weak talk to your doctor or pharmacist.

In order to minimise gastrointestinal side-effects, **ETHIONAMIDE MACLEODS 250 mg TABLETS** may be taken at bedtime or in divided doses with meals.

Your doctor may prescribe pyridoxine (Vitamin B<sub>6</sub>) to prevent damaging nervous tissue (brain and peripheral nerves).

Tablets should not be divided.

#### **Adults:**

15 – 20 mg/kg/day. Maximum of four tablets per day.

**Children:**

*Over 10 years:* Same as per adult dose.

*Under 10 years:* As determined by your doctor.

**Do not stop taking ETHIONAMIDE MACLEODS 250 mg TABLETS because you feel better.**

If the full treatment prescribed by your doctor is not completed, some of the bacteria causing the TB infection may not be killed. These bacteria may continue to grow and multiply so the TB infection may not clear completely or it may return.

**If you take more ETHIONAMIDE MACLEODS 250 mg TABLETS than you should**

In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

Too much **ETHIONAMIDE MACLEODS 250 mg TABLETS** can increase the intensity of side effects.

**If you forget to take ETHIONAMIDE MACLEODS 250 mg TABLETS**

If you have missed a dose of **ETHIONAMIDE MACLEODS 250 mg TABLETS**, take it as soon as you remember. However if it is almost time for your next dose, skip the missed dose and go back to your regular scheduling. Never double your dose.

**POSSIBLE SIDE-EFFECTS**

**ETHIONAMIDE MACLEODS 250 mg TABLETS** can have side-effects.

**If any of the following happens, stop taking ETHIONAMIDE MACLEODS 250 mg TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- swelling of face, tongue or throat
- difficulties in swallowing

- hives and difficulties in breathing
- severe skin reactions that can include blistering of the skin.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ETHIONAMIDE MACLEODS 250 mg TABLETS**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- low blood platelet count resulting in bleeding or bruising more easily than normal with red, pinpoint-sized rash
- low blood sugar (e.g., increased heartbeat, headache, chills, sweating, tremor, increased hunger, changes in vision, nervousness, weakness, dizziness, drowsiness, fainting)
- hypothyroidism (under functioning thyroid which leads to weight gain, lack of energy, thinning of hair, drying of skin and slowed mentality)
- goiter (abnormal swelling of the thyroid gland that causes a lump to form in the neck)
- mental illness
- seizures
- tingling of hands or feet
- vision changes (e.g., loss of vision)
- yellowing of the skin or eyes (signs of inflammation of the liver); blood tests may reveal increase in liver enzymes.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following side-effects and they worry you or if any of these symptoms are severe or do not go away:

- feeling depressed, anxious, restless
- dizziness, drowsiness, headache
- double or blurred vision

- low blood pressure when standing up from sitting or lying down; this may make you feel faint or dizzy
- nausea, diarrhoea, vomiting, stomach pain, increased salivation, metallic taste, mouth sores, loss of appetite, weight loss
- hair loss, increased sensitivity of the skin to sunlight, acne, red and inflamed skin with itchy rash
- joint pain
- enlarged breasts, inability to maintain an erection in men, absence of monthly period in women
- weakness

Not all the side-effects reported for **ETHIONAMIDE MACLEODS 250 mg TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ETHIONAMIDE MACLEODS 250 mg TABLETS**, please consult your doctor, pharmacist or health care professional for advice.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **STORAGE AND DISPOSING OF ETHIONAMIDE MACLEODS 250 mg TABLETS**

Store at or below 30 °C.

Keep strip pack in carton and sachet in HDPE container until required for use. The HDPE container must be kept well closed.

Store this medicine away from light and moisture.

Any expired or outdated medicines and unused medicines can be returned to your nearest pharmacy.

Do not dispose of unused medicines in drains or sewerage systems e.g. toilets.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

#### **PRESENTATION OF ETHIONAMIDE MACLEODS 250 mg TABLETS**

A soft tempered silver aluminium strip containing 14 tablets. Strips are packed in a pre-printed outer carton. Pack sizes: 14's, 28's, 56's and 84's.

Silver aluminium sachet (PET/Al/LLDPE), kept in a white plastic container (HDPE), which is sealed at the mouth with an aluminium tagger and is closed with a white HDPE screw-on lid.

Pack size: 250 tablets.

#### **IDENTIFICATION OF ETHIONAMIDE MACLEODS 250 mg TABLETS**

Yellow circular biconvex film-coated tablets with plain surface on both sides.

#### **REGISTRATION NUMBER**

49/20.2.3/0894

#### **NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER**

MACLEODS PHARMACEUTICALS SA (PTY) LTD

Stand 6D&E

Growthpoint Business Park

Tonetti Street

Halfway House

Midrand

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