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 Cycloserine Capsules is and what it is used for
2. Before you take Cycloserine Capsules
3. How to take Cycloserine Capsules
4. Possible side effects
5. How to store Cycloserine Capsules
6. Further information

1. WHAT CYCLOSERINE CAPSULES IS AND WHAT IT IS USED FOR

Cycloserine Capsules is used to treat tuberculosis (TB) caused by *Mycobacterium tuberculosis*. It is always given together with other medicines for TB. Cycloserine, the active ingredient of Cycloserine Capsules, belongs to the family of medicines called antibiotics.

To help clear up your tuberculosis (TB) completely, you must keep taking this medicine for the full time of treatment, even if you begin to feel better. This is very important. It is also important that you do not miss any doses.

2. BEFORE YOU TAKE CYCLOSERINE CAPSULES

Do not take Cycloserine Capsules:

- if you are hypersensitive (allergic) to cycloserine or any of the other ingredients of Cycloserine Capsules (see section 6, What Cycloserine Capsules contains),
- if you have seizures (epilepsy),
- if you have a psychiatric disorder (e.g. depressions or anxiety disorder),
- if you drink alcohol regularly.

Take special care with Cycloserine Capsules

Cycloserine Capsules may severely affect your mind and nervous system (see “Possible side effects”). Your doctor will regularly check for these symptoms. If you or your contacts notice any undue depression or personality change while you are taking cycloserine, report this immediately to your doctor or health care provider.

If you experience rash or yellowing of the skin and eyes (possible signs of an allergic reaction), tell your doctor immediately.

Discuss the use of Cycloserine Capsules with your doctor or health care provider if you have kidney disease. Your doctor may need to adjust your dose.

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 a prescription. These may affect the action of Cycloserine Capsules, or Cycloserine Capsules may affect their action.

Concurrent use of Cycloserine Capsules with isoniazid or ethionamide (other antituberculosis medicines) may make the side effects on the central nervous system worse. Your doctor may adjust the dosage of the antituberculosis medicines and will regularly check for these side effects.

Do not drink alcohol while taking Cycloserine Capsules. You are more likely to experience serious side effects such as seizures if you drink alcohol while taking this medicine. Also, alcohol may make side effects of cycloserine such as dizziness and drowsiness more severe.

**Taking Cycloserine Capsules with food and drink**
Cycloserine can be taken with or without food.

**Pregnancy and breast-feeding**
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.

Cycloserine passes into the breast milk. However, no negative effects have been reported in breast-fed-infants, whose mothers were receiving cycloserine.

**Driving and using machines**
Cycloserine Capsules may cause side effects such as dizziness or drowsiness, that can impair your ability to drive and to use machines.

3. **HOW TO TAKE CYCLOSERINE CAPSULES**
Always take Cycloserine Capsules 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 Cycloserine Capsules 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 dose is one capsule (250 mg) taken twice daily (in the morning and evening) in the beginning of treatment. Often this dose is used throughout the treatment course, but your doctor may also slowly increase your dose to one capsule (250 mg) taken three or four times per day. The doses should be taken evenly distributed over the day (while you are awake).

For children the dose must be determined by the doctor that prescribes the drug. Doses of 10 mg per kilogram (4.5 mg per pound) of body weight per day have been used.

Cycloserine Capsules will always be taken in combination with other medicines against tuberculosis; please make sure to follow the instructions within the supplied package leaflet(s).

**If you take more Cycloserine Capsules than you should**
If you have taken too many tablets you may develop headaches, dizziness, confusion, drowsiness, hyper-irritability, numbness or tingling in your hands or feet, slurred speech and personality changes (psychosis). You should immediately contact your doctor, health care provider or the nearest hospital emergency department for further advice.
If you forget to take Cycloserine Capsules
Take the missed dose as soon as possible, unless your next dose is scheduled in less than six hours.
Skip the missed dose if it is almost time for your next regular dose.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking Cycloserine Capsules
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, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Cycloserine Capsules can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by Cycloserine Capsules, 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 (greater than 1 in every 100 patients treated) side effects are:
- confusion or abnormal behaviour,
- numbness or tingling in your hands or feet,
- tremors (shaking),
- drowsiness,
- dizziness,
- difficulty speaking,
- irritability,
- headache.

There are rare reports (between 1 in 10 000 and 1 in 1000 patients treated) of:
- allergic reactions (difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; skin rash or hives).
- cardiac arrhythmias and sudden development of congestive heart failure in patients receiving 1 g or more per day.

Epileptic seizures and coma have been reported in patients treated with cycloserine. However, frequency estimates for these effects are not available:

Call your doctor right away if you notice any of these side effects.

5. HOW TO STORE CYCLOSERINE CAPSULES
Keep out of the reach and sight of children.
Store in the original package below 25°C.
Do not use Cycloserine Capsules after the expiry date which is stated on the strip.
Do not use Cycloserine Capsules if you notice brittle or swollen capsule.
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 Cycloserine Capsules contains
The active ingredient is cycloserine.

Information on excipients removed upon request of the company.

What Cycloserine Capsules looks like and contents of the pack
Maroon/ maroon size ‘1’ Hard Capsule
Aluminium foil/ Aluminium foil strip of 10 capsules. Such 9 or 10 strips in a carton box.
Aluminium / Aluminium cold form blister of 10 capsules. Such 9 or 10 blisters in a carton box.

Supplier
Macleods Pharmaceuticals Ltd.
304, Atlanta Arcade,
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Tel: 0091 22 6676 2800
Fax: 0091 22 2821 6599
E-mail: exports@macleodspharma.com

Manufacturers
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Survey no. 366
Premier Industrial Estate
Kachigam
396 210 Daman
India

Macleods Pharmaceuticals Limited,
Village Theda,
Baddi Industrial Estate Area, PO Lodhi Majra,
Tehsil: Nalagarh,
Solan district, Himachal Pradesh, 174101, India

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

<table>
<thead>
<tr>
<th>CAMBODIA</th>
<th>MYANMAR</th>
<th>MALAYSIA</th>
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| Curewel International Co ltd
No.34, Street 208,
Sangket 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 |

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<th>THAILAND</th>
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<table>
<thead>
<tr>
<th>Country</th>
<th>Company Name</th>
<th>Address/Location</th>
<th>Phone/Fax Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethiopia</td>
<td>General Chemicals &amp; Trading Pvt. Ltd. Co.</td>
<td>P.O.Box 5620, Addis Ababa, Ethiopia.</td>
<td>Tel: +256-41-346670 / 251067; Fax: +256-41-346680</td>
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<tr>
<td>Kenya</td>
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<td>Tel: 00254 20 3753004/5/6; Fax: 00254 20 3752200</td>
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<td>Medivation (Pty) Limited No. 6 Copper str.</td>
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</tr>
<tr>
<td>Uganda</td>
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<td>Tel: +256-41-346670 / 251067; Fax: +256-41-346680</td>
</tr>
<tr>
<td>Zambia</td>
<td>Prime Pharmaceuticals Limited</td>
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<td>Tel: 002601-220207; Fax: 002601-293458</td>
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<td>Tel: +375 17 211 6292; Fax: +375 17 260 8533</td>
</tr>
<tr>
<td>Russia</td>
<td>Advanced Trading Corporation Limited</td>
<td>27,Dmitrovskoye Shosse,Korpus:1,Office: 1028,29 and 30 Moscow,Russia-127550</td>
<td>Tel: +7 (095) 782 92 87 or 782 92 95; Fax: +7 (095) 782 92 29</td>
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<td>Tel: (+ 995 32) 23 01 06; Fax: (+ 995 32) 25 00 61</td>
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<td>Kyrgyzstan</td>
<td>INTERPHARMA</td>
<td>902 Vikram Towers, 16 Rajendra Place, New Delhi 110 008</td>
<td>Tel: 011-25869291/25863290/51538617</td>
</tr>
<tr>
<td>Colombia</td>
<td>VESALIUS PHARMA LTD</td>
<td>A.CRA. 19 C NO. 86-14 OF. 602 EDIFICIO PARMA, BOGOTA, D.C. - COLOMBIA</td>
<td>Tel: 003120-4033051; Fax: 03120-4031854</td>
</tr>
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<td>The Netherlands</td>
<td>International Dispensary Association</td>
<td>P.O.Box 37098, 1030 AB Amsterdam, The Netherlands.</td>
<td>Tel: 003120-4033051; Fax: 03120-4031854</td>
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<tr>
<td>Denmark</td>
<td>Mission Pharma</td>
<td>A/S.Vassingeroedvej 9. DK-3540 Lyne DENMARK.</td>
<td>Tel: 45 48163200; Fax: 45 48163248</td>
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This leaflet was last approved in November 2007. Section 6 updated in July 2015.

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