

**PATIENT INFORMATION LEAFLET**

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

### Cycloserine 250 mg capsules\*

Cycloserine 250 mg capsules

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Cycloserine 250 mg capsules is and what it is used for
2. What you need to know before you take Cycloserine 250 mg capsules
3. How to take Cycloserine 250 mg capsules
4. Possible side effects
5. How to store Cycloserine 250 mg capsules
6. Contents of the pack and other information

#### 1. WHAT CYCLOSERINE 250 MG CAPSULES IS AND WHAT IT IS USED FOR

Cycloserine 250 mg 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 250 mg 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. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CYCLOSERINE 250 MG CAPSULES

Do not take Cycloserine 250 mg capsules:

- if you are hypersensitive (allergic) to cycloserine or any of the other ingredients of Cycloserine 250 mg capsules (see section 6, What Cycloserine 250 mg capsules contains),
- if you have seizures (epilepsy),
- if you have a psychiatric disorder (e.g. depression or anxiety disorder),
- if you drink alcohol regularly.

#### Warnings and precautions

Cycloserine 250 mg capsules may severely affect your mind and nervous system (see “Possible side effects”). Your health care provider 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 health care provider.

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

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\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority’s responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Discuss the use of Cycloserine 250 mg capsules with your health care provider if you have kidney disease. Your health care provider may need to adjust your dose.

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

### **Other medicines and Cycloserine 250 mg capsules**

Tell your health care provider or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. These may affect the action of Cycloserine 250 mg capsules, or Cycloserine 250 mg capsules may affect their action.

Concurrent use of Cycloserine 250 mg capsules with isoniazid or ethionamide (other antituberculosis medicines) may make the side effects on the central nervous system worse. Your health care provider may adjust the dosage of the antituberculosis medicines and will regularly check for these side effects.

### **Cycloserine 250 mg capsules with food, drink and alcohol**

Do not take Cycloserine 250 mg capsules with a high-fat meal. The absorption of cycloserine may be negatively affected. Cycloserine should best be taken without food.

It can be taken with orange juice.

Do not drink alcohol while taking Cycloserine 250 mg 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 (see “Do not take Cycloserine 250 mg capsules”).

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

If you are pregnant, think you may be pregnant or are planning to have a baby, you must contact your 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. If the infant is breastfed both the breast feeding mother and the infant should be dosed with Vitamin B6.

### **Driving and using machines**

Cycloserine 250 mg capsules may cause side effects such as dizziness or drowsiness, that can impair your ability to drive and to use machines.

### **Cycloserine 250 mg capsules contains ponceau 4R (cochineal red A).**

This medicinal product contains ponceau 4R (cochineal red A), which may cause allergic reactions.

## **3. HOW TO TAKE CYCLOSERINE 250 MG CAPSULES**

Always take this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Your health care provider will assign the dose of Cycloserine 250 mg 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 health care provider tells you to do so.

Body weight	30-55.9 kg	56-70.9 kg	> 70 kg
Daily dose	500 mg	750 mg	1000 mg
Number of capsules per day	2	3	4

This dose is either split up to be taken twice daily (in the morning and evening) or once daily if tolerated.

For children the dose will be determined by the health care provider that prescribes the drug. Doses of 10-20 mg per kilogram of body weight per day have been used (daily maximum 1000 mg). The following information includes only the average doses of this medicine.

Body weight	5 kg	6-9.9 kg	10-11.9 kg	12-22.9 kg	23-30 kg
Daily dose, per 250 mg capsule	0.25	0.5	0.75	1.0	2.0
1 capsule in 10 ml water	2.5 ml	5.0 ml	7.5 ml	10.0 ml*	_*

\* For older children who cannot swallow capsules, the capsules can be opened and dissolved in 10 ml water to aid administration.

Pyridoxine (Vitamin B6) should be taken concomitantly with cycloserine. If the mother is breastfeeding her infant, the infant should also be dosed with Vitamin B6.

Cycloserine 250 mg capsules will always be taken in combination with other medicines against tuberculosis; please make sure to follow the instructions within the supplied patient information leaflet(s).

#### **If you take more Cycloserine 250 mg capsules than you should**

If you have taken too many capsules 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 health care provider or the nearest hospital emergency department for further advice.

#### **If you forget to take Cycloserine 250 mg 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 a forgotten dose.

#### **If you stop taking Cycloserine 250 mg capsules**

Do not stop treatment unless your health care provider tells you to, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Cycloserine 250 mg 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 250 mg capsules, and those caused by any other medicines you may be taking at the same time, or by the disease itself.

For this reason, it is important that you inform your 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,
- depression
- lethargy
- nervousness
- 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, increased light sensitivity of the skin or inflammation of the liver).
- irregular heart beat and sudden development of heart failure (your heart muscle doesn't pump blood as well as it should) in patients receiving 1 g or more per day.

Frequency estimates for the following effects are not available:

- Vitamin B12 deficiency, folic acid deficiency, potentially leading to anaemia, which is characterized by many large immature and dysfunctional red blood cells (megaloblasts), other forms of anaemia.
- Elevated liver enzymes, particularly in patients with pre-existing liver disease.
- Involuntary rhythmic jerking movements of the arms and legs (clonic seizures), convulsion, coma, slight or partial paralysis, extremely high fever
- skin rash, which can be life-threatening and also involve the mucous membranes (Stevens-Johnson syndrome)

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

## **5. HOW TO STORE Cycloserine 250 mg capsules**

Keep this medicine out of the sight and reach of children.

Do not store above 25°C, store in a dry place. Keep the bottle tightly closed to protect from moisture. Protect from light.

Discard the product 50 days after initial opening.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Cycloserine 250 mg capsules contains**

The active ingredient is 250 mg cycloserine.

The other ingredients are:

Capsule content: Talc.

Capsule shell composition: Gelatine, Ponceau 4R E124 (cochineal red A), Quinoline yellow E104, Titanium dioxide E171

### **What Cycloserine 250 mg capsules looks like and contents of the pack**

Cycloserine 250 mg capsules is a hard gelatine capsule No. 0 with white body and orange cap, filled with a white or almost white powder.

Cycloserine 250 mg capsules is provided in HDPE bottle with HDPE screw cap, provided with a tamper-proof ring and induction foil sealing. 1 bottle with a leaflet in a carton.

Pack size: 21 or 100 capsules.

### Supplier and Manufacturer

Supplier	Manufacturer
Biocom JSC 54 Chapaevsky Cr 355016 Stavropol Russian Federation TEL : +78652365356 Email: biocom@biocom.ru	Biocom JSC 54 Chapaevsky Cr 355016 Stavropol Russian Federation TEL : +78652365356 Email: biocom@biocom.ru

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

**This leaflet was last approved in February 2016**

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