

## Package leaflet: Information for the user

### Cycloserine 250 mg Hard Capsules cycloserine

**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 doctor or pharmacist.
- 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 doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What Cycloserine is and what it is used for

Cycloserine capsules contain the active ingredient cycloserine, which is an antibiotic.

Cycloserine is used to treat tuberculosis (TB) together with other medicines. It is also used to treat infections of the urinary tract.

#### 2. What you need to know before you take Cycloserine

##### Do not take Cycloserine

- if you are allergic to cycloserine or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- if you have epilepsy
- if you suffer from depression
- if you have severe anxiety or psychosis (abnormal thoughts)
- if you have a severe kidney disease
- if you are an alcoholic.

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Cycloserine

- if you suffer from porphyria (a disorder affecting the red blood cells).

##### Other medicines and Cycloserine

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

In particular, talk to your doctor if you are taking any of the following medicines:

- Ethioamide, isoniazid (for tuberculosis [TB]).

It may still be alright for you to be given Cycloserine and your doctor will be able to decide what is suitable for you.

##### Cycloserine with alcohol

Alcohol should be avoided whilst taking this medicine.

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Cycloserine has no effect on your ability to drive or use machines.

### **Cycloserine capsules contain sunset yellow FCF (E110) and carmoisine (E122)**

Sunset yellow FCF (E110) and carmoisine (E122) may cause allergic reactions.

## **3. How to take Cycloserine**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 500 mg to 1 g daily in divided doses.

**Use in adults:** the usual starting dose for adults is 250 mg every twelve hours for the first two weeks. The maximum daily dose is 1 g.

**Use in elderly:** elderly patients with kidney disease will need a reduced dose.

**Use in children:** The usual starting dose for children is 10 mg per kg of body weight per day and then adjusted depending on the response.

The capsules should be swallowed whole with water.

### **If you take more Cycloserine than you should**

Go to the nearest hospital casualty department or contact your doctor immediately. Take the carton with you.

### **If you forget to take Cycloserine**

If you miss a dose, take one as soon as you can. Do not take a double dose to make up for a forgotten dose. If you have missed several doses, tell your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Very serious side effects**

All medicines can cause allergic reactions.

**Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching, especially affecting your whole body.**

### **Reported side effects (the frequency cannot be estimated from available data)**

- sudden shortness of breath (heart failure) – in patients receiving 4-6 capsules of cycloserine daily (1-1.5 g daily)
- coma
- headache
- feeling drowsy or very sleepy
- shaking
- dizziness
- confusion
- hallucination

- loss of memory
- slurred speech
- fits
- pins and needles in your hands and/or feet
- loss of use of your arms or legs
- twitching and muscle stiffness
- character and mood changes including feeling irritable and aggressive
- suicidal thoughts
- anemia
- abnormalities of liver function

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Cycloserine**

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

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

Store below 25°C. Keep the bottle tightly closed in order to protect from moisture.

Do not throw away any medicines via wastewater or 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 capsules contain**

- The active substance is cycloserine. Each hard capsule contains 250 mg of the active substance cycloserine.
- The other ingredients are: Talc, Erythrosin (E127), Carmoisine (E122) (see section 2), Sunset Yellow FCF (E110) (see section 2), Titanium Dioxide (E171), Black Iron Oxide (E172) and Gelatin.

#### **What Cycloserine capsules look like and contents of the pack**

Cycloserine capsules are red and grey and come in plastic bottles containing 100 capsules. Each bottle also contains a desiccant which has a label stating 'Do not eat'.

#### **Marketing Authorisation Holder**

Neon Healthcare Ltd, 8 The Chase, John Tate Road, Hertford, SG13 7NN, UK

#### **Manufacturer**

Custom Pharmaceuticals Ltd  
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or

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