

## **Package leaflet: Information for the user**

### **OPTIMAX 500MG CAPSULES**

L-tryptophan

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

#### **1. What Optimax is and what it is used for**

- The name of your medicine is Optimax 500mg capsules, which will be referred to as Optimax throughout this leaflet. Optimax contains the active substance L-tryptophan. L-tryptophan belongs to a group of medicines called antidepressants.
- Optimax is used in adults for treatment-resistant depression. This means that it is used together with other antidepressants in people who have tried these alone for a period of time, but have failed to recover.

#### **2. What you need to know before you take Optimax**

##### **Do not take Optimax:**

- If you are allergic to L-tryptophan or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include skin rash, swelling of the face, wheezing or difficulty breathing.
- If you have had eosinophilia myalgia syndrome (EMS, a blood problem that increases white blood cells called eosinophilia and causes severe muscle pain) after taking any form of L-

tryptophan (the active ingredient in Optimax).

## Warnings and precautions

Talk to your doctor or pharmacist before taking Optimax.

### Take special care with Optimax and tell your doctor if you:

- have problems with your liver, blood or kidneys
- have ever had thoughts about killing or harming yourself (see the following section)
- are under age 25 (see the following section)

### Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks, but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

**You may find it helpful to tell a relative or close friend** that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think that your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

## Children

Optimax is not recommended for children.

## Other medicines and Optimax

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

Usually Optimax is only prescribed by your doctor together with other medicines to treat your depression. Taking Optimax may worsen the side effects of the other medicines. These include:

- Monoamine oxidase inhibitors (MAOIs), such as phenelzine and moclobemide, and tranylcypromine.
- 5-HT reuptake inhibitors (also called serotonin inhibitors, selective serotonin reuptake inhibitors or SSRIs) such as citalopram, dapoxetine, paroxetine, and fluoxetine. With SSRIs, a problem called **serotonin syndrome** can occur. The potential for this may also occur with SNRIs (serotonin/norepinephrine reuptake inhibitors) such as duloxetine, and the appetite suppressant sibutramine. Serotonin syndrome can cause agitated behavior, sleeplessness, aggression, sickness, diarrhoea, stomach pain, poor coordination and headache. **Please consult your doctor if you notice any of these symptoms.**
- levodopa, a medicine used in the treatment of Parkinson's disease, may be less effective if used at the same time as Optimax.
- antipsychotic (phenothiazine) or anti-anxiety (benzodiazepine) drugs, such as chlorpromazine and diazepam. These have caused loss of the usual social inhibitions about sexual matters.

### **Optimax with food and drink**

You should **avoid drinking alcohol** during treatment with anti-depressants.

### **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. Optimax should not be taken when breast-feeding.

### **Driving and using machines**

L-tryptophan may cause drowsiness. When you first start to take Optimax you should avoid driving or operating machinery until you know whether your alertness is affected.

### **3. How to take Optimax**

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 capsules should be swallowed whole, preferably after food.

The recommended dose is for:

#### Adults

The usual starting dose is two capsules, three times a day (morning, midday and evening). This may be increased to four capsules, three times a day if your doctor thinks it is necessary.

#### Elderly

Your doctor may tell you to take fewer capsules each day.

### **Duration of treatment:**

Take your capsules for as long as your doctor says. You may need to take Optimax for many months, it may take some time for the capsules to work.

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

Too much of this medicine can make you drowsy and feel sick. If you or anyone else takes too much of this medicine, contact your doctor or hospital immediately. Take this leaflet with you to show what you have swallowed.

### **If you forget to take Optimax**

Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Optimax**

Talk to your doctor before you stop taking Optimax and follow their advice.

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.

If you experience any of the following side effects with Optimax, **STOP taking the capsules and contact your doctor immediately**: A severe allergic reaction, such as itching, swelling of the face, lips, tongue, mouth, or throat, which may cause shortness of breath, wheezing, or difficulty breathing.

Very rarely, the active ingredient in Optimax has caused a disease called Eosinophilia Myalgia Syndrome (EMS). **If you develop symptoms of fever, muscle or joint pains or a rash, you should see your doctor as soon as possible.**

The following side effects have been reported:

- feeling sick (nausea)
- headache
- light headedness
- suicidal thoughts or behaviour (see section 2)

#### Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

[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 Optimax

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

This medicinal product does not require any special storage conditions.

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

Use within three months of the first opening.

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 Optimax contains

The active substance is 500 mg L-tryptophan. The other ingredients are povidone, sodium starch glycolate, silica colloidal anhydrous, magnesium stearate and silicon dioxide. The capsule shell consists of gelatin and titanium dioxide (E171).

##### What Optimax looks like and contents of the pack

Optimax are white capsules.

Optimax is available in plastic containers of 84 capsules.

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**This leaflet was last revised in March 2022.**