

<b>Product Name:</b> ELMOX 500 (AMOXICILLIN CAPSULES BP)	
<b>Dosage Form:</b> Capsules for Oral administration	
<b>Patient Information leaflet (PIL)</b>	



## **Patient information leaflet-Elmox 500 (Amoxicillin Capsules BP)**

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 (or for your child) 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

The name of your medicine is Amoxicillin Capsules BP 500mg.

### **What is in this leaflet:**

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

### **1. What Amoxicillin Capsules is and what it is used for**

#### **What Amoxicillin Capsules is**

Amoxicillin Capsules is an antibiotic. The active ingredient is Amoxicillin Capsules. This belongs to a group of medicines called 'penicillins'.

#### **What Amoxicillin Capsules is used for**

Amoxicillin Capsules is used to treat infections caused by bacteria in different parts of the body. Amoxicillin Capsules may also be used in combination with other medicines to treat stomach ulcers.

### **2. What do you need to know before you take Amoxicillin capsules**

#### **Do not take Amoxicillin Capsules:**

- If you are allergic to Amoxicillin Capsules, penicillin or any of the other ingredients of this medicine.
- If you have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat.

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Do not take Amoxicillin Capsules if any of the above applies. If you are not sure, talk to your doctor or pharmacist before taking Amoxicillin Capsules.

### **Warnings and Precautions**

Talk to your doctor or pharmacist before taking Amoxicillin Capsules if you:

- have glandular fever (fever, sore throat, swollen glands and extreme tiredness)
- have kidney problems
- are not urinating regularly

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Amoxicillin Capsules.

### **Blood and urine tests**

If you are having:

- Urine tests (glucose) or blood tests for liver function
- Oestriol tests (used during pregnancy to check the baby is developing normally)

Tell your doctor or pharmacist that you are taking Amoxicillin Capsules. This is because Amoxicillin Capsules can affect the results of these tests.

### **Other medicines and Amoxicillin Capsules**

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

- If you are taking allopurinol (used for gout) with Amoxicillin Capsules, it may be more likely that you will have an allergic skin reaction.
- If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Amoxicillin Capsules.
- If you are taking medicines to help stop blood clots (such as warfarin), you may need extra blood tests.
- If you are taking other antibiotics (such as tetracycline) Amoxicillin Capsules may be less effective.
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) Amoxicillin Capsules may cause an increase in side effects.

### **Taking Amoxicillin Capsules with food and drink**

Amoxicillin Capsules do not have known interactions with food or drink.

### **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.

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### **Driving and using machines**

Amoxicillin Capsules can have side effects and the symptoms (such as allergic reactions, dizziness and convulsions) may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

### **3. How to take Amoxicillin capsules**

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

- Swallow with water without opening capsule.
- Space the doses evenly during the day, at least 4 hours apart

The recommended dose is:

### **Children weighing less than 40 kg**

All doses are worked out depending on the child's body weight in kilograms.

- Your doctor will advise you how much Amoxicillin Capsules you should give to your baby or child.
- The usual dose is 40 mg to 90 mg for each kilogram of body weight a day, given in two or three divided doses.
- The maximum recommended dose is 100 mg for each kilogram of body weight a day.


### **Adults, elderly patients and children weighing 40 kg or more**

The usual dose of Amoxicillin Capsules is 250 mg to 500 mg three times a day or 750 mg to 1 g every 12 hours, depending on the severity and type of infection.

- **Severe infections:** 750 mg to 1 g three times a day.
- **Urinary tract infection:** 3 g twice daily for one day.
- **Lyme disease (an infection spread by parasites called ticks):** Isolated erythema migrans (early stage – red or pink circular rash): 4 g a day, Systemic manifestations (late stage – for more serious symptoms or when the disease spreads around your body): up to 6 g a day.
- **Stomach ulcers:** one 750 mg or one 1 g dose twice a day for 7 days with other antibiotics and medicines to treat stomach ulcers.
- **To prevent heart infection during surgery:** the dose will vary according to the type of surgery. Other medicines may also be given at the same time. Your doctor, pharmacist or nurse can give you more details.
- The maximum recommended dose is 6 g per day.

### **Kidney problems**

If you have kidney problems the dose might be lower than the usual dose.

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### **If you take more Amoxicillin Capsules than you should**

If you have taken too much Amoxicillin Capsules, signs might be an upset stomach (feeling sick, being sick or diarrhoea) or crystals in the urine, which may be seen as cloudy urine, or problems passing urine.

Talk to your doctor as soon as possible. Take the medicine to show the doctor.

### **If you forget to take Amoxicillin Capsules**

- If you forget to take a dose don't worry, take it as soon as you remember.
- Don't take the next dose too soon, wait about 4 hours before taking the next dose.
- Do not take a double dose to make up for a forgotten dose.

### **How long should you take Amoxicillin Capsules for?**

- Keep taking Amoxicillin Capsules for as long as your doctor has told you to, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.
- Once you finish treatment, if you still feel unwell you should go back to see the doctor.

Thrush (a yeast infection of moist areas of the body which can cause soreness, itching and white discharge) may develop if Amoxicillin Capsules is used for a long time. If this occurs, tell your doctor.

If you take Amoxicillin Capsules for a long time, your doctor may perform additional tests to check your kidneys, liver and blood are working normally.

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

## **4. Possible side effects**

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

### **Stop taking Amoxicillin Capsules and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:**

The following are very rare (may affect up to 1 in 10,000 people)

- Allergic reactions, the signs may include: skin itching or rash, swelling of the face, lips, tongue, body or breathing difficulties. These can be serious and occasionally deaths have occurred
- Rash or pinpoint flat red round spots under the skin surface or bruising of the skin. This is due to inflammation of blood vessel walls due to an allergic reaction. It can be associated with joint pain (arthritis) and kidney problems
- A delayed allergic reaction can occur usually 7 to 12 days after having Amoxicillin Capsules, some signs include: rashes, fever, joint pains and enlargement of the lymph nodes especially under the arms

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- A skin reaction known as ‘erythema multiforme’ where you may develop: itchy reddish purple patches on the skin especially on the palms of the hands or soles of the feet, ‘hive-like’ raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and private parts. You may have a fever and be very tired
- Other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These may be associated with fever, headaches and body aches
- Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).
- High temperature (fever), chills, a sore throat or other signs of an infection, or if you bruise easily. These may be signs of a problem with your blood cells
- The *Jarisch-Herxheimer reaction* which occurs during treatment with Amoxicillin Capsules for Lyme disease and causes fever, chills, headache, muscle pain and skin rash.
- Inflammation of the large bowel (colon) with diarrhoea sometimes containing blood, pain and fever
- Serious liver side effects may occur which are often reversible. Hepatitis and cholestatic jaundice, they are mainly associated with people having treatment over a long period, males and the elderly. You must tell your doctor urgently if you get:
  - Severe diarrhoea with bleeding
  - Blisters, redness or bruising of the skin
  - Darker urine or paler stools
  - Yellowing of the skin or the whites of the eyes (jaundice). See also anaemia below which might result in jaundice.

These can happen when having the medicine or for up to several weeks after.

**If any of the above happen stop taking the medicine and see your doctor straight away.**

**Sometimes you may get less severe skin reactions such as:**

- A mildly itchy rash (round, pink-red patches), ‘hive-like’ swollen areas on forearms, legs, palms, hands or feet. This is uncommon (affects less than 1 in 100 people).

**If you have any of these talk to your doctor as Amoxicillin Capsules will need to be stopped.**

The following side effects have been reported at the approximate frequencies shown:

Common (may affect up to 1 in 10 people):

- Diarrhoea
- Skin rash
- Feeling sick (nausea)

Uncommon (may affect up to 1 in 100 people):

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- Being sick (vomiting)

Very Rare (may affects up to 1 in 10,000 people):

- Thrush (a yeast infection of the vagina, mouth or skin folds), you can get treatment for thrush from your doctor or pharmacist
- Kidney problems
- Fits (convulsions), seen in patients on high doses or with kidney problems
- Dizziness
- Hyperactivity
- Crystals in the urine, which may be seen as cloudy urine, or difficulty or discomfort in passing urine. Make sure you drink plenty of fluids to reduce the chance of these symptoms
- The tongue may change to yellow, brown or black and it may have a hairy appearance
- An excessive breakdown of red blood cells causing a form of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes
- The blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself.
- Low number of white blood cells
- Low number of cells involved with blood clotting

### **5. How to store Amoxicillin capsules**

Amoxicillin capsules BP 500mg should be store below 30°C, in a dry place. It should be kept out of reach of children.

### **6. Further information**

#### **What Amoxicillin Capsules contains:**

- The *active* ingredient is Amoxicillin Capsules (as Amoxicillin trihydrate)
- The other ingredients are Magnesium Stearate.

#### **What Amoxicillin Capsules looks like and contents of the pack:**

**Elmox 500** (Amoxicillin Capsules BP 500mg) is a White crystalline powder filled in Brown/Yellow coloured “0” size printed Hard Gelatin Capsules. Such 10 capsules are Blister packed in Alu-PVC blister pack (Primary packing) and 10 of such Blisters are packed in the outer carton with pack insert (Secondary packing).

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**Name and address of the manufacturer:**

YELURI FORMULATIONS PVT LTD

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Sangareddy District - 502 325,

Telangana, India.

**Name and address of the marketing authorization holder:**

Sun enterprises Ltd

B.P 933, Kigali, Rwanda