

## Package leaflet: Information for the patient

### Amoxiclav Elpen 875 mg/125 mg poeder voor orale suspensie in sachet Amoxicillin/Clavulanic acid

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

#### 1. What Amoxiclav Elpen is and what it is used for

Amoxiclav Elpen is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called 'penicillins' that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

Amoxiclav Elpen is used in adults and children to treat the following infections:

- Middle ear and sinus infections
- Respiratory tract infections
- Urinary tract infections
- Skin and soft tissue infections including dental infections
- Bone and joint infections

#### 2. What you need to know before you take Amoxiclav Elpen

##### Do not take Amoxiclav Elpen:

- if you are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

##### Do not take Amoxiclav Elpen if any of the above apply to you.

If you are not sure, talk to your doctor or pharmacist before taking this medicine.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- Have glandular fever
- Are being treated for liver or kidney problems
- Are not passing water regularly

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Amoxiclav Elpen.

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of Amoxiclav Elpen or a different medicine.

#### **Conditions you need to look out for**

Amoxicillin/clavulanic acid can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while you are taking Amoxiclav Elpen, to reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

#### **Blood and urine tests**

If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are taking Amoxiclav Elpen. This is because Amoxicillin/clavulanic acid can affect the results of these types of tests.

#### **Other medicines and Amoxicillin/clavulanic acid**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.

If you are taking allopurinol (used for gout) with Amoxiclav Elpen, it may be more likely that you will have an allergic skin reaction.

If you are taking probenecid (used for gout), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended.

If medicines to help stop blood clots (such as warfarin) are taken with Amoxiclav Elpen then extra blood tests may be needed.

Amoxiclav Elpen can affect how methotrexate (used to treat cancer or severe psoriasis) works. Penicillins may reduce the excretion of methotrexate causing a potential increase in side effects.

Amoxiclav Elpen may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

#### **Pregnancy, breast-feeding and fertility**

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**

Amoxiclav Elpen can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

#### **Amoxiclav Elpen contains Aspartame**

This medicine contains 12.5 mg aspartame in each sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

### **3. How to take Amoxiclav Elpen**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if

you are not sure.

#### **Adults and children weighing 40 kg and over**

- The usual dose: 1 sachet of 875 mg/125 mg two times a day
- Higher dose: 1 sachet of 875/125 mg three times a day

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

Amoxiclav Elpen 875 mg/125 mg powder for oral suspension in sachet is not recommended for children weighing less than 40 kg.

#### **Patients with kidney and liver problems**

- If you have kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor.
- If you have liver problems you may have more frequent blood tests to check how your liver is working.

#### **How to take Amoxiclav Elpen**

- Just before you need to take Amoxiclav Elpen, open the sachet and mix the contents in half a glass of water. Stir the mixture well and drink it immediately.
- Take with a meal
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Amoxiclav Elpen for more than two weeks. If you still feel unwell you should go back to see the doctor.

#### **If you take more Amoxiclav Elpen than you should**

If you take too much Amoxiclav Elpen, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible. Take the medicine carton to show the doctor.

#### **If you forget to take Amoxiclav Elpen**

If you forget to take a dose, take it as soon as you remember. You should not take the next dose too soon, but wait about 4 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Amoxiclav Elpen**

Keep taking Amoxiclav Elpen until the treatment is finished, 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.

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

#### **4. Possible side effects**

Like all medicines, Amoxiclav Elpen can cause side effects, although not everybody gets them.

#### **Conditions you need to look out for**

##### **Allergic reactions:**

- Skin rash
- Inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- Fever, joint pain, swollen glands in the neck, armpit or groin
- Swelling, sometimes of the face or throat (angioedema), causing difficulty in breathing
- Collapse
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)

**Contact a doctor immediately if you get any of these symptoms.  
Stop taking Amoxiclav Elpen.**

### **Inflammation of large intestine**

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

Acute inflammation of the pancreas (acute pancreatitis)

If you have severe and on-going pain in the stomach area this could be a sign of acute pancreatitis.

Drug-induced enterocolitis syndrome (DIES):

DIES has been reported mainly in children receiving amoxicillin/clavulanate. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4hours after drug administration). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.

**Contact your doctor as soon as possible for advice if you get these symptoms.**

### **Very common side effects**

These may affect more than 1 in 10 people

- Diarrhoea (in adults)

### **Common side effects**

These may affect up to 1 in 10 people

- Thrush (*candida* – a yeast infection of the vagina, mouth or skin folds)
- Feeling sick (nausea), especially when taking high doses
  - **if affected take Amoxiclav Elpen with a meal**
- Vomiting
- Diarrhoea (in children)

### **Uncommon side effects**

These may affect up to 1 in 100 people

- Skin rash, itching
- Raised itchy rash (hives)
- Indigestion
- Dizziness
- Headache

Uncommon side effects that may show up in your blood tests:

- Increase in some substances (enzymes) produced by the liver.

### **Rare side effects**

These may affect up to 1 in 1000 people

- Skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – erythema multiforme)

**If you notice any of these symptoms contact a doctor urgently.**

Rare side effects that may show up in your blood tests:

- Low number of cells involved in blood clotting
- Low number of white blood cells.

### **Other side effects**

Other side effects have occurred in a very small number of people but their exact frequency is not known.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)

- Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- Serious skin reactions:
  - A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface – toxic epidermal necrolysis)
  - Widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis)
  - A red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis)
  - 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))
- **Contact a doctor immediately if you get any of these symptoms.**
- Inflammation of the liver (hepatitis)
- Jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
- Inflammation of tubes in the kidney
- Blood takes longer to clot
- Hyperactivity
- Convulsions (in people taking high doses of Amoxiclav Elpen or who have kidney problems)
- Black tongue which looks hairy
- Stained teeth (in children), usually removed by brushing

Side effects that may show up in your blood or urine tests:

- Severe reduction in the number of white blood cells
- Low number of red blood cells (haemolytic anaemia)
- Crystals in urine leading to acute kidney injury

### **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 national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Amoxiclav Elpen**

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

Do not store this medicine above 30°C. Store in the original package in order to protect from moisture.

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

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 Amoxiclav Elpen contains:**

- The active substances are amoxicillin and clavulanic acid

Each sachet contains: amoxicillin trihydrate equivalent to 875 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid.

- The other excipients are: Silica colloidal hydrated, aspartame and orange flavour.

### **What Amoxiclav Elpen looks like and contents of the pack**

Amoxiclav Elpen 875 mg/125 mg powder for oral suspension in sachet is a white to off-white powder packed in paper-aluminium-polyethylene foil sachets.

Pack sizes of 10, 12 and 20 sachets in a carton box.

Not all pack-sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

ELPEN Pharmaceutical Co. Inc.  
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19009, Pikermi Attica  
Griekenland

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

The Netherlands: Amoxiclav Elpen 875 mg/125 mg poeder voor orale suspensie  
Germany: Amoxiclav-Elpen 875 mg/125 mg Pulver zur Herstellung einer Suspension

### **Deze bijsluiter is voor het laatst goedgekeurd in januari 2023**

#### **Advice/medical education**

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help to prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.