

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed according to a physician's prescription only

## Augmentin 500 mg Tablets

### Film-coated tablets

Each tablet contains:

500 mg amoxicillin (as trihydrate)

125 mg clavulanic acid (as potassium salt)

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – “Important information about some of the ingredients in the medicine” and section 6 – “Additional information”.

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

Augmentin 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.

Augmentin is an antibiotic that 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” whose action can sometimes be stopped (become inactive). The other active component (clavulanic acid) prevents this from happening.

**Therapeutic group:**

Amoxicillin: Penicillin antibiotic group.

Clavulanic acid: Beta-lactamase enzyme inhibitors.

## 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

- you are sensitive (allergic) to amoxicillin, clavulanic acid, penicillin or to any of the additional ingredients contained in this medicine (listed in section 6).
  - 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.
  - you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.
- **Do not take Augmentin if any of the above apply to you.** If you are not sure, talk to your physician or pharmacist before taking Augmentin.

**Special warnings regarding use of the medicine**

**Before the treatment with Augmentin, tell the physician if:**

- you have glandular fever
- you are being treated for liver or kidney problems
- you are not passing water **properly**.

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

In some cases, your physician may check the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of Augmentin or a different medicine.

**Conditions you need to look out for**

Augmentin 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

Augmentin, 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 undergoing blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the physician know that you are taking Augmentin. This is because Augmentin can affect the results of these types of tests.

### **Drug interactions**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.**

- If you are taking allopurinol (used for treatment of gout) with Augmentin, it may be more likely that you will have an allergic skin reaction.
- If you are taking probenecid (used for treatment of gout), your physician may decide to adjust the dose of Augmentin.
- If medicines that prevent blood clotting (such as warfarin or acenocoumarol) are taken with Augmentin then extra blood tests may be needed.
- Augmentin can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
- Augmentin may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

### **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 physician for advice before using this medicine.

### **Driving and using machines**

Augmentin can have side effects and the symptoms may make you unfit to drive.

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

## **Important information about some of the ingredients in the medicine**

### **Augmentin 500 mg Tablets contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet and is therefore considered sodium-free.

## **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

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

The recommended dosage is usually:

- 1 tablet three times a day.

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

Children aged 6 years or less should preferably be treated with Augmentin oral suspension. Consult with the physician when giving tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 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 physician.
- If you have liver problems you may have more frequent blood tests to check your liver function.

**Do not exceed the recommended dose.**

### **How to take Augmentin**

- Take with a meal.
- Swallow the tablets whole with a glass of water.
- Tablets can be halved along the score line to ease swallowing. You must take both pieces of the tablet at the same time. There is no information regarding crushing or chewing.

- Space the doses evenly throughout the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Augmentin for more than 2 weeks. If you still feel unwell you should go back to see the physician.

#### **If you accidentally have taken a higher dosage**

If you accidentally have taken too much Augmentin, the signs might include stomach discomfort (nausea, vomiting or diarrhoea) or convulsions. Refer to your physician as soon as possible. Take the medicine package to show the physician.

If a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

#### **If you forgot to take the medicine**

- If you forgot 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.

Adhere to the treatment regimen recommended by your physician.

#### **If you stop taking the medicine**

Keep taking Augmentin until the treatment is finished, even if you feel better. Each dose is important for you in order to help fight the infection. If some bacteria survive, they can cause the infection to come back.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the physician or pharmacist.**

## **4. SIDE EFFECTS**

As with any medicine, use of Augmentin may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from

any of them. The side effects below may happen with this medicine.

**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 physician immediately** if you experience any of these symptoms.  
**Stop taking Augmentin.**

**Inflammation of the large intestine**

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

**Drug-induced enterocolitis (inflammation of the intestine) syndrome (DIES)**

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

**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.

- **Contact your physician as soon as possible** for advice if you experience these symptoms.

## Side effects according to their frequency:

### 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 fungal infection of the vagina, mouth or skin folds)
- nausea, especially when taking high doses  
→ if nausea occurs, take Augmentin 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 liver enzymes.

### Rare side effects

These may affect up to 1 in 1,000 people:

- skin rash, which may include blisters (looks like 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 physician 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.

**Side effects of unknown frequency (frequency cannot be estimated from the available data)**

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Drug-induced enterocolitis (inflammation of the intestine) syndrome (DIES) (see above)
- Acute inflammation of the pancreas (acute pancreatitis) (see above)
- Inflammation of the membrane that surround the brain and spinal cord (*aseptic meningitis*)

- **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 (*exanthematous pustulosis*)
  - Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including an increase in the amount of white blood cells [eosinophilia] and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms [*DRESS*])
  - a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck (Symmetrical Drug-Related Intertriginous and Flexural Exanthema [*SDRIFE*]).
- **Contact a physician immediately if you experience any of these symptoms.**
- inflammation of the liver (*hepatitis*)
  - jaundice, caused by an increase of bilirubin (a substance produced in the liver) in the blood which may cause yellowing of the skin and whites of the eyes
  - inflammation of tubes in the kidney

- longer blood clotting time
- hyperactivity
- convulsions (in people taking high doses of Augmentin or who have kidney problems)
- black tongue which looks hairy.
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).

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.

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.**

### **Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

## **5. HOW TO STORE THE MEDICINE?**

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Tablets supplied in an aluminium pouch should be used within 30 days of opening the pouch.

- Store in the original package in order to protect from moisture.
- Do not use if the tablets are chipped or damaged.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

## 6. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains:

Tablet core –

Microcrystalline cellulose, sodium starch glycolate (Type A), colloidal anhydrous silica and magnesium stearate.

Film-coat –

Hypromellose (5 cps, 15 cps), titanium dioxide (E171), macrogol (4000, 6000) and dimeticone.

- What the medicine looks like and the contents of the package:

Augmentin 500 mg film-coated tablets are white to off-white, oval shaped tablets, debossed with “AC” and a score line on one side.

They are packaged in:

- blister packs, in a carton package. Each carton contains 20 tablets.

Or

- blister packs inside aluminium pouches, enclosed in a carton package. The pouch contains a desiccant sachet. The desiccant must be kept inside the pouch and must not be swallowed. Each carton contains 20 tablets.

Not all package sizes may be marketed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
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