

**PATIENT LEAFLET 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 a list of the inactive and allergenic ingredients in the preparation – see section 2 “Important information about some of the ingredients of the medicine” and section 6 “Additional information”.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the 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 any of the additional ingredients contained in the 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 the use of the medicine

Talk to your physician or pharmacist before taking Augmentin 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, have recently taken or might take other medicines including non-prescription medicines, herbal medicines and nutritional supplements, tell the physician or the 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 become pregnant, ask your physician or pharmacist for advice before taking 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 of 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 this preparation as per the physician's instructions. Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

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

Adults and children weighing 40 kg and over

The usual dosage is generally:

- 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 Augmentin

- 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.

Persist with the treatment as recommended by the physician.

If you stop taking Augmentin

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 the use of the medicine, consult the physician or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Augmentin may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience 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*])
 - rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).
- **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.

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 has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking the link “Report Side Effects of Drug Treatment” that is located on the Ministry of Health home page (www.health.gov.il), which refers to on-line form for side effects reporting, 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 without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing 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 waste water or household waste. Consult the pharmacist regarding how to discard medicines that are not in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- What Augmentin contains:

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 does the medicine look like and what is the content 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.
- **Manufacturer:** GlaxoSmithKline Trading Services Limited, Dublin, Ireland.
- Revised in August 2023 according to MOH guidelines.
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026-27-25048.
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