

Patient leaflet in accordance with the  
Pharmacists' Regulations (Preparations) – 1986

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

# Augmentin Suspension 250 mg/5 ml

## **Powder for preparation of oral suspension**

Each 5 ml of suspension contains:

250 mg amoxicillin (as trihydrate)

62.50 mg clavulanic acid (as potassium salt)

Each 1 ml of suspension contains:

50 mg amoxicillin (as trihydrate)

12.5 mg clavulanic acid (as potassium salt)

A list of the additional ingredients is detailed in section 6.

**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 pharmacist.

This medicine has been prescribed for you/your child. 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, children and babies 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

## 2. Before using the medicine

### Do not use the medicine if:

- you or your child are/is sensitive (allergic) to amoxicillin, clavulanic acid, penicillin or any of the additional ingredients contained in the medicine (listed in section 6)
  - you or your child have/has ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat
  - you or your child have/has ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.
- **Do not take Augmentin or do not give Augmentin to your child if any of the above apply to you or to your child.** If you are not sure, talk to the physician or pharmacist before taking/giving Augmentin.

### Special warnings regarding use of the medicine

Check with the physician or pharmacist before giving your child Augmentin or taking Augmentin if:

- you or your child have/has glandular fever
- **you or your child** are/is being treated for liver or kidney problems
- you or your child are/is not passing water **properly**.

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

In some cases, the physician may check the type of bacteria that is causing the infection. Depending on the results, you or your child 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 or your child are/is 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 or your child are/is 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/he

are/is taking Augmentin. This is because Augmentin can affect the results of these types of tests.

### **Other medicines and Augmentin**

If you/your child are/is taking, have/has recently taken or might take other medicines, including non-prescription medicines, herbal medicines and nutritional supplements, tell the physician or the pharmacist. Especially:

- If you/your child are/is taking allopurinol (used for gout) with Augmentin, it may be more likely that you/he will have an allergic skin reaction.
- If you/your child are/is taking probenecid (used for gout), the physician may decide to adjust the dose of Augmentin.
- If medicines that help 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, breast-feeding and fertility**

If you/your child who is about to take this medicine are/is pregnant or breast-feeding, think/thinks you/she may be pregnant or are/is 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 contains aspartame, benzyl alcohol and maltodextrin.

- This medicine contains 2.5 mg aspartame (E951) in each 1 ml. Aspartame is a source of phenylalanine. This may be harmful for patients suffering from “phenylketonuria”, a rare genetic disorder in which phenylalanine accumulates because the body cannot clear it properly.
- Augmentin contains traces of benzyl alcohol. Benzyl alcohol may cause allergic reactions.
- Augmentin contains maltodextrin (glucose). If you have been told by the physician that your child/you has/have an intolerance to certain sugars, contact the physician

before giving/taking this medicine.

### **3. How should you use the medicine?**

Always use the 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 by the physician only. The usual dosage is generally:

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

- This suspension is not usually recommended for adults and children weighing 40 kg and over. Ask the physician or pharmacist for advice.

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

All doses are calculated on the basis of body weight in kilograms.

- Your physician will advise you how much Augmentin you should give to your baby or child.
- You may be provided with a plastic measuring spoon or plastic measuring cup or dosing syringe. You should use this to give the correct dose to your baby or child.

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

- If you or your child have/has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by the physician.
- If you or your child have/has liver problems you/he may have more frequent blood tests to check your/his liver function.

#### **Do not exceed the recommended dose**

Opening instructions: To remove the cap, press down and twist to the left (turning counter-clockwise) at the same time.

Closing instructions: Close the bottle tightly with the cap, twisting to the right (turning clockwise) until fully closed.

#### **Instructions for reconstitution**

- Remove the cap and check that the foil-backed bottle seal is intact before using
- Shake the bottle to loosen the powder and remove the foil-backed seal
- Add the volume of water indicated below, close, invert and shake well.
- To prepare 100 ml suspension, add 90 ml water.

#### **How to give Augmentin**

- Always shake the bottle well before each dose

- Give/take with a meal
- Space the doses evenly throughout the day, at least 4 hours apart. Do not take/give to your child 2 doses in 1 hour.
- Do not give your child/take Augmentin for more than 2 weeks. If your child/you still feels/feel unwell he/you should go back to see the physician.

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

If you accidentally have given your child/taken too much Augmentin, the signs might include stomach discomfort (nausea, vomiting or diarrhoea) or convulsions. Refer to the 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 give/take Augmentin**

If you forgot to give your child a dose or forgot to take a dose, give/take it as soon as you remember. You should not give your child/take the next dose too soon, but wait about 4 hours before giving/taking the next dose. Do not give/do not take a double dose to make up for a forgotten dose.

Persist with the treatment as recommended by the physician.

#### **If you/your child stop/stops taking Augmentin**

Keep giving your child/taking Augmentin until the treatment is finished, even if he/you feels/feel better. Each dose is important for your child/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/Your child 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.
- **Contact a physician immediately** if you/your child experience/s any of these symptoms. **Stop taking/giving 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.

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

### **Additional side effects**

#### **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/give 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 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 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)
  - Inflammation of the protective membrane surrounding the brain (*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*]).
- **Contact a physician immediately if you/your child experience/s any of these symptoms.**
- inflammation of the liver (*hepatitis*)
  - jaundice, caused by an increase of bilirubin in the blood (a substance produced in the liver) which may make your child's/your skin and whites of the eyes appear yellow
  - 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
- stained teeth (in children), usually removed by brushing.

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

- severe reduction in the number of white blood cells
- low number of red blood cells (*haemolytic anaemia*)
- crystals in urine.

**If a side effect has appeared, if one of the side effects worsens or when your child/you suffers/suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician.**

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 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.

### **Dry powder**

Store in the original container to protect from moisture.

Store below 25°C.

### **Liquid suspension**

Store in a refrigerator (between 2°C to 8°C).

Do not freeze.

Once prepared, the suspension should be used within 7 days.

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

- In addition to the active ingredients the medicine also contains:  
Hydroxypropyl methylcellulose (Hypromellose), silicon dioxide (anhydrous), colloidal anhydrous silica, xanthan gum, aspartame, succinic acid, golden syrup dry flavour\*, raspberry dry flavour\*, orange dry flavour 1\* (includes benzyl alcohol), orange dry flavour 2\*.  
(\*also includes maltodextrin).

See also *'important information about some of the ingredients of the medicine'* in section 2.

- What does the medicine look like and what is the content of the package:  
Child-resistant bottle packaging.  
Augmentin suspension 250 mg/5 ml is a white-off-white powder supplied in a clear glass bottle. Once prepared, the bottle contains 100 ml of a white-off-white liquid mixture called a suspension.
- License Holder and address: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer and address: GlaxoSmithkline Trading Services Limited, Dublin, Ireland.
- Revised in April 2023 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:  
Augmentin Suspension 250 mg/5 ml: 026-28-25050

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