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

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

Augmentin Suspension 400 mg/5 ml

Powder for preparation of oral suspension

Each 5 ml of suspension contains:

400 mg amoxicillin (as trihydrate)

57 mg clavulanic acid (as potassium salt)

Each 1 ml of suspension contains:

80 mg amoxicillin (as trihydrate)

11.4 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/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

- recurrent tonsil infections.

There are no clinical data for patients under two months of age.

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 or your child are/is sensitive (allergic) to amoxicillin, clavulanic acid, penicillin or to any of the additional ingredients contained in this 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

Before taking Augmentin or giving your child Augmentin, tell the physician 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 your 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 (to check glucose levels), let the physician know that you/he are/is taking Augmentin. This is because Augmentin can affect the results of these types of tests.

Drug interactions

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

- If you/your child are/is taking allopurinol (used for treatment of gout) with Augmentin, it may be more likely that you/your child will have an allergic skin reaction.
- If you/your child are/is taking probenecid (used for treatment of gout), the 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/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 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 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 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. The recommended dosage is usually:

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 syringe. Instructions for use of the dosing syringe are provided at the end of this leaflet. You should use them to give the correct dose to your baby or child.
- There are no clinical data for patients under two months of age.

Patients with kidney and liver problems

- If you/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, there may be need for more frequent blood tests to check 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.

How to give/take Augmentin

- Always shake the bottle well before each dose.
- Give/take at the start of a meal or slightly before.
- Space the doses evenly throughout the day, at least 4 hours apart. Do not take/give your child 2 doses in one hour.
- Do not give your child/take Augmentin for more than two weeks. If your child/you still feel/feels unwell he/you should go back to see the physician.

If you accidentally have given/taken a higher dosage

If you have accidentally given your child/taken too much Augmentin, the signs might include stomach discomfort (nausea, vomiting or diarrhoea) or

convulsions. Refer to a physician as soon as possible. Take the medicine bottle 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 the medicine

- 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.

Adhere to the treatment regimen recommended by your physician.

If you/your child stop/stops taking the medicine

Keep giving your child/taking Augmentin until the treatment is finished, even if your child/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 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/your child 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/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.

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

Side effects according to their frequency:

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 before food

- 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)
- 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/your child experience/s 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 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.
- 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 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 your child/you suffers/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) 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.
- **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.
  After preparation, the suspension should be used within 7 days.
- 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.

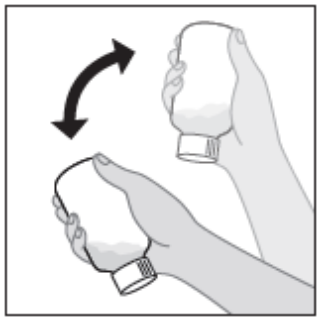
6. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains:
  Silicon dioxide (anhydrous), hydroxypropylmethylcellulose dried (hypromellose), colloidal anhydrous silica, golden syrup dry flavour*, raspberry dry flavour*, orange dry flavour 1* (includes benzyl alcohol), xanthan gum, aspartame (E951), orange dry flavour 2*, succinic acid.
  (*also includes maltodextrin)
  See also *'Important information about some of the ingredients in the medicine'* in section 2.
- What the medicine looks like and the contents of the package:
  Child-resistant bottle packaging.
  Augmentin suspension 400 mg/5 ml (fruit-flavoured) powder for oral suspension is a white to off-white powder supplied in a clear glass bottle. After preparation, the bottle contains 35 ml, 70 ml or 140 ml of a white to tan liquid mixture called a suspension.
  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 December 2024.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 112-75-29288

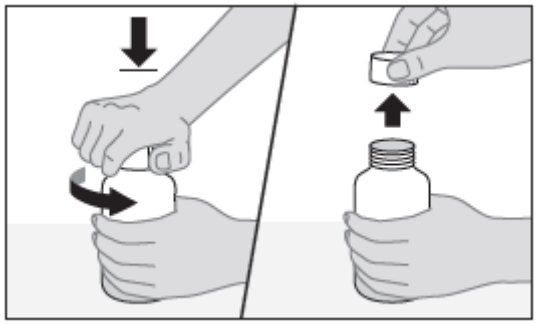
Instructions for preparation:

Remove the bottle cap. Check foil-backed seal is intact before use. Replace the bottle cap.

1. Shake the bottle to loosen the powder.



2. Remove the bottle cap.



3. Peel back the foil-backed seal to remove it.

4. Add volume of water (as indicated below). Replace bottle cap, invert and shake well.
   To prepare a suspension in the 35 ml package, add 31 ml water.
   To prepare a suspension in the 70 ml package, add 62 ml water.
   To prepare a suspension in the 140 ml package, add 124 ml water.
5. Store in the refrigerator and shake well before every use.
   After preparation, use the suspension within 7 days.

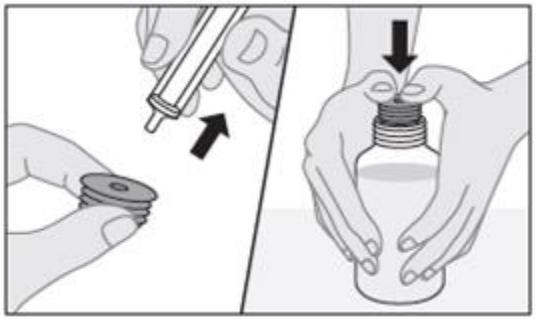
Instructions for using the dosing syringe

A syringe is supplied to administer Augmentin

The syringe is only for use with Augmentin and must not be used to administer any other medicines, because the markings are specific to this product. The syringe is supplied with an adaptor which allows it to be attached to the bottle. The dose is indicated on the oral dosing syringe in milliliters (ml). You should take/give your child the dose recommended by the physician.
Check the cleanliness of syringe and adaptor before use, rinse with clean water if required.

1. Shake the bottle of suspension well before each dose.

2. Remove the adaptor from the syringe. Hold the bottle firmly and insert the adaptor into the neck of the bottle (the adaptor should remain in place).



3. Insert the syringe into the adaptor ensuring it is secure.

4. Invert the bottle holding the syringe in place and withdraw the required dose as indicated by your physician.

5. Place the bottle upright and remove the syringe.

6. To take/give the dose, carefully put the tip of the syringe into the mouth and slowly push down on the plunger of the syringe (repeat steps 3, 4, 5 and 6 if more than one syringe is needed to deliver the dose).

7. Rinse the syringe thoroughly in clean water. Allow the syringe to dry completely before the next use.

8. Replace the bottle cap.

9. Store in the refrigerator and shake well before every use.
   After preparation, the suspension should be used within 7 days.