PACKAGE LEAFLET

Package leaflet: Information for the user

Augmentin Duo 400 mg/57 mg/5 ml Powder for Oral Suspension (mixed fruit flavour)

amoxicillin/clavulanic acid

Read all of this leaflet carefully before you start giving your child this medicine because it contains important information for them.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine is usually prescribed for a child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Augmentin is and what it is used for

Augmentin 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.

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.

2. What you need to know before you give Augmentin

Do not give your child Augmentin:
- if they are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6).
- if they 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 they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

➔ **Do not give Augmentin to your child if any of the above apply to your child.** If you are not sure, talk to their doctor or pharmacist before giving Augmentin.

Warnings and precautions
Check with their doctor, pharmacist or nurse before giving your child Augmentin if they:
- 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 your child, talk to their doctor or pharmacist before giving Augmentin.

In some cases, your doctor may investigate the type of bacteria that is causing your child's infection. Depending on the results, 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 your child is taking Augmentin, to reduce the risk of any problems. See '*Conditions you need to look out for'* in **Section 4**.

Haemophagocytic lymphohistiocytosis (HLH)
A rare condition in which the immune system makes too many of otherwise normal infection fighting cells called histiocytes and lymphocytes. It can lead to enlarged liver and/or spleen, heart problems and kidney abnormalities. Symptoms may include fever, skin rash, problems related to nerves, swollen lymph glands, breathing problems and easy bruising. Tell your doctor immediately if your child experiences these symptoms at the same time.

Blood and urine tests
If your child is 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 they are taking Augmentin. This is because Augmentin can affect the results of these types of tests.

Other medicines and Augmentin
Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

If your child is taking allopurinol (used for gout) with Augmentin, it may be more likely that they will have an allergic skin reaction.

If your child is taking probenecid (used for gout), your doctor may decide to adjust the dose of Augmentin.

If medicines to help stop blood clots (such as warfarin) 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 can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy, breast-feeding and fertility
If your child who is about to take this medicine is pregnant or breast-feeding, thinks they may be pregnant or are planning to have a baby, ask their doctor 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.

Augmentin contains aspartame, benzyl alcohol and maltodextrin

- This medicine contains 2.5 mg aspartame in each ml. Aspartame is a source of phenylalanine. It may be harmful for children born with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains 0.003 mg benzyl alcohol in each ml. Benzyl alcohol may cause allergic reactions.

- Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children.
- Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.
- Ask your doctor or pharmacist for advice if you are pregnant, breast-feeding or have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
- Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to give Augmentin

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children weighing 40 kg or over

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

Children weighing less than 40 kg

All doses are worked out depending on the child's bodyweight in kilograms.

- Your doctor will advise you how much Augmentin you should give to your child.
- You may be provided with a plastic measuring spoon or syringe. Instructions on how to use the dosing syringe are provided at the end of this leaflet. You should use this to give the correct dose to your child.
- Recommended dose – 25 mg/3.6 mg/kg/day (0.4 ml of suspension/kg/day) to 45 mg/6.4 mg/kg/day (0.6 ml of suspension/kg/day) given in two divided doses
- Higher dose – up to 70 mg/10 mg/kg/day (1.0 ml of suspension/kg/day) given in two divided doses.

Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems they may have more frequent blood tests to see how their liver is working.

How to give Augmentin

- Always shake the bottle well before each dose
- Give at the start of a meal or slightly before
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

If you give more Augmentin than you should

If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to give Augmentin

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

If your child stops taking Augmentin
Keep giving your child Augmentin until the treatment is finished, even if they feel better. Your child needs 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 medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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 doctor immediately** if your child gets any of these symptoms. **Stop taking Augmentin.**

Haemophagocytic lymphohistiocytosis (HLH), a condition where the immune system makes too many of otherwise normal infection-fighting cells called histiocytes and lymphocytes.
Symptoms can include:
- fever
- skin rash
- problems related to nerves, such as shaking or tremor, confusional state
- swollen lymph glands
- breathing problems
- easy bruising.

➔ **Contact a doctor immediately** if your child gets any of these symptoms.

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

Drug-induced enterocolitis 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 doctor as soon as possible** for advice if your child gets these symptoms.

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 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 some substances (*enzymes*) produced by the liver.

Rare side effects
These may affect up to 1 in 1 000 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 blood tests:
- low number of cells involved in blood clotting
- low number of white blood cells.

Frequency not known
Frequency cannot be estimated from the available data.
- Allergic reactions (see above)
- Serious immune system condition (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the membranes 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 (*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)*)
  - 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 doctor immediately if your child gets any of these symptoms.**

- rash with blisters arranged in a circle with central crusting or like a string of pearls (*linear IgA disease*)
- inflammation of the liver (*hepatitis)*
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your child's 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 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*)
- high blood level of protein that stores iron in the body (in connection with HLH, see above)
- high blood levels of triglycerides, a type of fat (in connection with HLH, see above)
- 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:
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Augmentin

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

Dry powder
Store in the original package in order to protect from moisture. Do not store above 25°C.

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

Liquid suspension
Store in a refrigerator (2°C – 8°C).
Do not freeze.

Once made up, the suspension should be used within 7 days.

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 to protect the environment.

6. Contents of the pack and other information

What Augmentin contains

- The active substances are amoxicillin and clavulanic acid. Each ml of suspension contains amoxicillin trihydrate equivalent to 80 mg amoxicillin and potassium clavulanate equivalent to 11.4 mg of clavulanic acid.
- The other ingredients are aspartame (E951), xanthan gum, silicon dioxide, colloidal anhydrous silica, succinic acid, hypromellose, orange dry flavour 1* (including benzyl alcohol), orange dry flavour 2*, raspberry dry flavour* and golden syrup dry flavour* (*also includes maltodextrin).
- See section 2 for further important information about aspartame, benzyl alcohol and maltodextrin in Augmentin.

What Augmentin looks like and contents of the pack

Augmentin 400 mg/57 mg/5 ml (mixed-fruit flavour) powder for oral suspension is a white to off-white powder supplied in a clear glass bottle. Once made up, the bottle contains 35 ml, 70 ml or 140 ml of a white to tan liquid mixture called a suspension.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
GlaxoSmithKline (Ireland) Ltd.
12 Riverwalk
Citywest Business Campus Dublin 24
Ireland

Manufacturer
Glaxo Wellcome Production
Z.I. de la Peyenniere
53100 Mayenne
France

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria – Augmentin 400 mg/57 mg/5 ml Pulver zur Herstellung einer Suspension zum Einnehmen Multifruchtgeschmack
Bulgaria – Аугментин 400 mg/57 mg/5 ml прах за перорална суспензия
Croatia – Augmentin 400 mg + 57 mg/5 ml prašak za oralnu suspenziju s okusom voća
Cyprus – Augmentin Mixed Fruit
Czech Republic – Augmentin
Estonia – Augmentin
France – Augmentin 80 mg - 11.4 mg par ml Poudre pour suspension buvable
Germany – Augmentan Kindersaft
Greece - Augmentin MF
Hungary – Augmentin DUO
Ireland – Augmentin Duo Mixed Fruit
Italy – Augmentin
Latvia – Augmentin Fruit 400 mg/57 mg/5 ml pulveris iekšķīgi lietojamas suspensijas pagatavošanai
Lithuania – Augmentin
Malta – Augmentin Duo Mixed Fruit
Norway – Augmentin
Poland – Augmentin MFF
Portugal – Augmentin Duo
Romania – Augmentin FP
Slovakia – Augmentin DUO s príchuťou miešaného ovocia
United Kingdom (Northern Ireland) – Augmentin Duo

This leaflet was last revised in September 2026.

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.

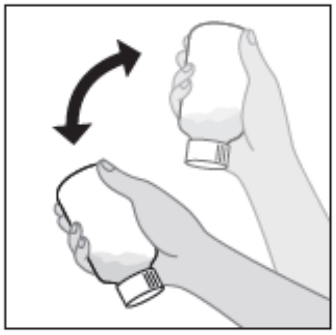
When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

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.

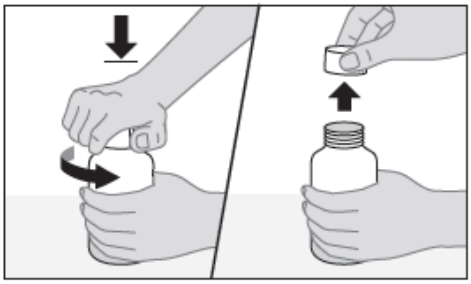
Instructions for reconstitution

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

1. Shake bottle to loosen powder.



2. Remove the bottle cap.



3. Peel back to remove foil-backed seal.



4. Add volume of water (as shown below). Replace bottle cap, invert and shake well.

Pack size (ml)	Volume of water to be added at reconstitution (ml)
35	31
70	62
140	124

Additional text for markets that have a fill line on the bottle or label:
Alternatively, fill the bottle with water to just below the line on the bottle or label. Replace the bottle cap, invert and shake well, then top up with water exactly to the line. Replace the bottle cap, invert and again shake well.

5. Store in a refrigerator and always shake before use.
   Once made up, the suspension should be used within 7 days.

Additonal text for markets which are supplied with a dosing syringe:
Instructions for using the syringe

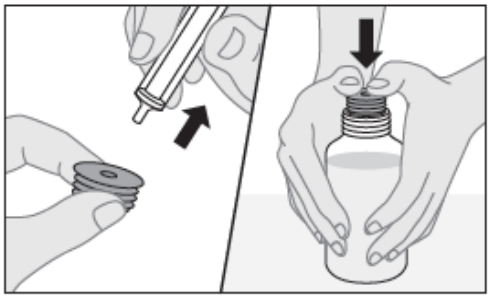
A syringe is supplied to administer Augmentin
The syringe is only for use with Augmentin and must not be used to administer any other medicines, because the markings are specific to this product. The syringe is supplied with an adaptor which allows it to attach to the bottle.

The dose is indicated on the oral dosing syringe in millilitres (ml). You should give your child the dose recommended by their doctor.

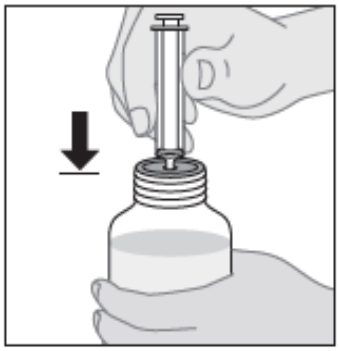
Check cleanliness of syringe and adaptor before use, rinse with clean water if required.

1. Shake the bottle suspension well before each dose.

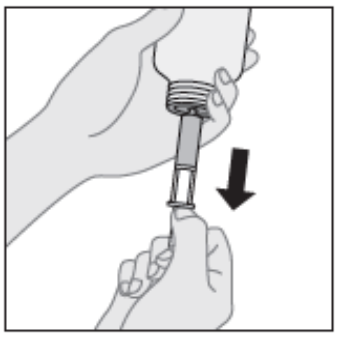
2. Remove adaptor from syringe. Hold the bottle firmly and insert the adaptor into the neck of the bottle (the adaptor should remain in place).



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



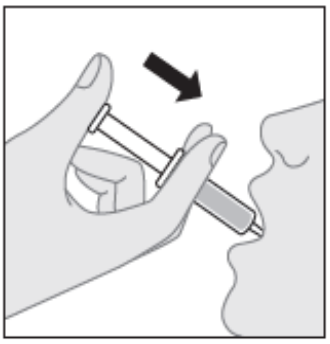
4. Invert bottle holding the syringe in place and withdraw the required dose as indicated by your doctor.



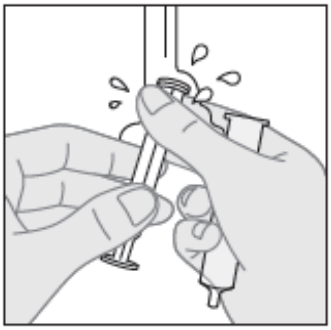
5. Place bottle upright and remove syringe.



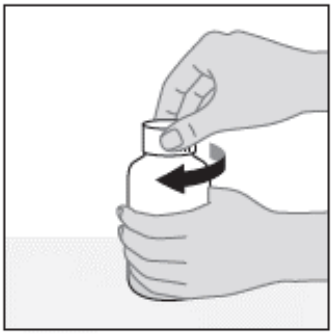
6. To give the dose, carefully put the tip of the syringe into the mouth and slowly push down on the plunger of the syringe (repeat steps 3, 4, 5 and 6 if more than one syringe is needed to deliver the dose).



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



8. Replace the bottle cap.



9. Store in a refrigerator and always shake before use.
   Once made up, the suspension should be used within 7 days.