

Package leaflet: Information for the user

Augmentin Intravenous 500 mg/100 mg powder for solution for injection/infusion Augmentin Intravenous 1000 mg/200 mg powder for solution for injection/infusion

amoxicillin/clavulanic acid

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your 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 have Augmentin
3. How Augmentin is given
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:

- severe ear, nose and throat infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections
- intra-abdominal infections
- genital organ infections in women.

Augmentin is used in adults and children to prevent infections associated with major surgical procedures.

2. What you need to know before you have Augmentin

You should not have Augmentin:

- if you are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6).
- if 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.
- if 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 doctor, pharmacist or nurse before having Augmentin.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before having Augmentin if you:

- 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 you, talk to your doctor, pharmacist or nurse before taking Augmentin.

In some cases, your doctor may investigate 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 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 you are taking Augmentin. This is because Augmentin can affect the results of these types of tests.

Other medicines and Augmentin

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

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

If you are taking probenecid (used for gout), your doctor may decide to adjust your 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 you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse 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 sodium and potassium

500 mg/100 mg powder for injection/infusion

- Augmentin 500 mg/100 mg contains approximately 31.4 mg (1.4 mmol) of sodium (the main component of cooking/table salt) per vial, which is equivalent to 1.6% of the recommended

maximum daily dietary intake of sodium for an adult. This should be considered if you are on a controlled sodium diet.

- Augmentin 500 mg/100 mg contains approximately 19.6 mg (0.5 mmol) of potassium per vial, which at less than 39 mg (1 mmol) is considered essentially 'potassium-free'.

1000 mg/200 mg powder for injection/infusion

- Augmentin 1000 mg/200 mg contains approximately 62.9 mg (2.7 mmol) of sodium (the main component of cooking/table salt) per vial or bottle, which is equivalent to 3.2% of the recommended maximum daily dietary intake of sodium for an adult. This should be considered if you are on a controlled sodium diet.
- Augmentin 1000 mg/200 mg contains approximately 39.3 mg (1.0 mmol) of potassium per vial or bottle. This should be considered by patients with kidney problems or patients on a controlled potassium diet.

3. How Augmentin is given

You will never give yourself this medicine. A qualified person, like a doctor or a nurse, will give you this medicine.

The recommended doses are:

Adults and children weighing 40 kg and over

Standard dose	1000 mg/200 mg every 8 hours.
To stop infections during and after surgery	<p>1000 mg/200 mg before the surgery when you are given your anaesthetic.</p> <p>The dose can differ depending on the type of operation you are having. Your doctor may repeat the dose if your surgery takes longer than 1 hour.</p>

Children weighing less than 40 kg

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

Children aged 3 months and over:	25 mg/5 mg for each kilogram of bodyweight every 8 hours.
Children aged less than 3 months or weighing less than 4 kg	25 mg/5 mg for each kilogram of bodyweight every 12 hours.

Patients with kidney and liver problems

- If you have kidney problems you may be given a different dose. A different strength or a different medicine may be chosen by your doctor.
- If you have liver problems your doctor will keep a close check on you and you may have more regular liver function tests.

How Augmentin will be given to you

- Augmentin will be given as an injection into a vein or by intravenous infusion.
- Make sure you drink plenty of fluids while having Augmentin.
- You will not normally be given Augmentin for longer than 2 weeks without the doctor reviewing your treatment.

If more Augmentin is given to you than recommended

It is unlikely you will be given too much, but if you think you have been given too much Augmentin, tell your doctor, pharmacist or nurse immediately. Signs may be an upset stomach (feeling sick, being sick or diarrhoea) or convulsions.

If you have any further questions about how this medicine is given, 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.

➔ **Contact a doctor immediately** if you get any of these symptoms. **Stop taking Augmentin.**

Inflammation of large intestine

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

➔ **Contact your doctor as soon as possible** for advice if you get 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)
- diarrhoea

Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised itchy rash (*hives*)
- feeling sick (nausea), especially when taking high doses

➔ if affected take Augmentin before food

- vomiting
- indigestion
- dizziness
- headache.

Uncommon side effects that may show up in your blood tests:

- increase in some substances (*enzymes*) produced by the liver.

Rare side effects

These may affect up to 1 in 1000 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.

- swelling and redness along a vein which is extremely tender when touched

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.

Frequency not known

Frequency cannot be estimated from 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 (*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)).
- ➔ Contact a doctor immediately if you get any of these symptoms.
- inflammation of the liver (*hepatitis*)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- convulsions (in people taking high doses of Augmentin or who have kidney problems).

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Augmentin

The expiry date and storage instructions stated on the label are for the doctor, nurse or pharmacist's information. The doctor, pharmacist or nurse will make up your medicine. It should be used within 20 minutes of reconstitution.

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

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

Do not store above 25°C.

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 protect the environment.

6. Contents of the pack and other information

What Augmentin contains

500 mg/100 mg powder for injection/infusion

- The active substances are amoxicillin and clavulanic acid. Each vial contains sodium amoxicillin equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 100 mg of clavulanic acid.

1000 mg/200 mg powder for injection/infusion

- The active substances are amoxicillin and clavulanic acid. Each vial or bottle contains sodium amoxicillin equivalent to 1000 mg amoxicillin and potassium clavulanate equivalent to 200 mg of clavulanic acid.

There are no other ingredients. However, see section 2 for further important information about sodium and potassium in Augmentin.

The doctor, nurse or pharmacist will make up the injection before use, using an appropriate fluid (such as Water for Injections or an injection/infusion fluid).

What Augmentin looks like and contents of the pack

Augmentin IV 500 mg/100 mg powder for solution for injection/infusion is supplied as clear glass vials of sterile powder for making up as an injection or infusion. The vials are supplied in packs of 1, 5 or 10.

Not all pack sizes may be marketed.

Augmentin IV 1000 mg/200 mg powder for solution for injection/infusion is supplied as clear glass vials or bottles of sterile powder for making up as an injection or infusion. The vials are supplied in packs of 1, 5, 10, 25 or 100. The bottles are supplied in packs of 5.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Product Authorisation Holder:

GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24.

Manufacturer: GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland *(for 500 mg/100 mg strength only)*

or

SmithKline Beecham Pharmaceuticals, Worthing, West Sussex, United Kingdom.

or

Biopharma S.r.l., Via delle Gerbere 22/30, 00134 Santa Palomba, Roma – Italy (*for 1000 mg/200 mg strength only*)

This medicinal product is authorised in the Member States of the EEA under the following names:

500 mg/100 mg powder for solution for injection/infusion

Cyprus – Augmentin

Czech Republic – Augmentin

France – Augmentin IV

Germany – Augmentan IV

Hungary – Augmentin

Iceland – Augmentin IV

Ireland – Augmentin Intravenous

Malta – Augmentin Intravenous

Netherlands – Augmentin

Slovenia – Augmentin

United Kingdom – Augmentin Intravenous

1000 mg/200 mg powder for solution for injection/infusion

Belgium – Augmentin

Czech Republic – Augmentin

Estonia – Augmentin

France – Augmentin IV

Germany – Augmentan IV

Greece – Augmentin

Hungary – Augmentin

Iceland – Augmentin IV

Ireland – Augmentin Intravenous

Italy – Augmentin

Latvia – Augmentin

Luxembourg – Augmentin

Malta – Augmentin Intravenous

Netherlands – Augmentin

Slovenia – Augmentin

Spain – Augmentine Intravenoso

United Kingdom – Augmentin Intravenous

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The following information is intended for healthcare professionals only:

Please refer to the Summary of Product Characteristics for further information

Administration

Augmentin may be administered either by slow intravenous injection over a period of 3 to 4 min directly into a vein or via a drip tube or by infusion over 30 to 40 min. Augmentin is not suitable for intramuscular administration.

Reconstitution

For single use only. Discard any unused solution.

The reconstitution/dilution is to be made under aseptic conditions. The solution is to be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

Augmentin IV vials or bottles are not suitable for multi-dose use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Preparation of solutions for intravenous injection

Water for Injection Ph.Eur. is the normal solvent.

Augmentin IV 500 mg/100 mg should be dissolved in 10 ml of solvent. This yields approximately 10.5 ml of solution for single-dose use.

Augmentin IV 1000 mg/200 mg should be dissolved in 20 ml of solvent. This yields approximately 20.9 ml of solution for single-dose use.

A transient pink colouration may or may not develop during reconstitution. Reconstituted solutions are normally colourless to yellow in colour.

Augmentin IV for bolus injection should be administered within 20 min of reconstitution.

Preparation of solutions for intravenous infusion

500 mg/100 mg powder for injection/infusion

Augmentin IV must be reconstituted as described above for injection.

Without delay the reconstituted solution should be added to 50 ml of infusion fluid using a minibag or in-line burette.

1000 mg/200 mg powder for injection/infusion

Augmentin IV must be reconstituted as described above for injection.

Without delay the reconstituted solution should be added to 100 ml of infusion fluid using a minibag or in-line burette.

Stability of prepared solutions

Reconstituted vials or bottles (for intravenous injection or before dilution for infusion)

500 mg/100 mg powder for injection/infusion

The reconstituted solution (1 vial with 10 ml of Water for Injections Ph.Eur.) should be used or diluted immediately, within 20 minutes.

1000 mg/200 mg powder for injection/infusion

The reconstituted solution (1 vial or bottle with 20 ml of Water for Injections Ph.Eur.) should be used or diluted immediately, within 20 minutes.

Diluted for intravenous infusion

500 mg/100 mg powder for solution for injection/infusion

Chemical and physical in-use stability has been demonstrated for 2-3 hours at 25°C, or 8 hours at 5°C. From a microbiological point of view, the reconstituted and diluted solution (1 reconstituted vial in a minimum volume of 50 ml of infusion fluid) should be used immediately.

1000 mg/200 mg powder for solution for injection/infusion

Chemical and physical in-use stability has been demonstrated for 2-3 hours at 25°C, or 8 hours at 5°C. From a microbiological point of view, the reconstituted and diluted solution (1 reconstituted vial or bottle in a minimum volume of 100 ml of infusion fluid) should be used immediately.

500 mg/100 mg, 1000 mg/200 mg powder for injection/infusion

Intravenous infusions of amoxicillin/clavulanate may be given in a range of different intravenous fluids. Satisfactory antibiotic concentrations are retained at 5°C and at room temperature (25°C) in the recommended volumes of the following infusion fluids. If reconstituted and maintained at room temperature (25°C), infusions should be completed within the times stated in the following table:

<u>Intravenous infusion</u>	<u>Stability period at 25°C</u>
Water for Injection Ph.Eur.	3 hours
0.9% w/v Sodium Chloride Intravenous Infusion (9 mg/ml)	3 hours
Compound Sodium Chloride Injection 1959 (Ringer's)	2 hours
Compound Sodium Lactate Intravenous Infusion (Ringer-Lactate:Hartmann's)	2 hours
0.3% w/v Potassium Chloride and 0.9% w/v Sodium Chloride Intravenous Infusion (3 mg/ml and 9 mg/ml)	2 hours

For storage at 5°C, reconstituted solutions of Augmentin IV may be added to pre-refrigerated infusion bags containing either Water for Injection Ph. Eur. or sodium chloride BP (0.9% w/v), which may be stored for up to 8 hours. Thereafter, the infusion should be administered immediately after reaching room temperature.

The stability of Augmentin IV solutions is concentration dependent. In the event that the use of more concentrated solutions is required, the stability period should be adjusted accordingly.

Augmentin IV is less stable in infusions containing glucose, dextran or bicarbonate. Reconstituted solutions of Augmentin may be injected into the drip tubing over a period of 3 to 4 min.

Any residual antibiotic solution should be discarded.

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