AUGMENTIN Injection
Potassium clavulanate/amoxicillin sodium equivalent to 100 mg clavulanic acid/500 mg amoxicillin
Potassium clavulanate/amoxicillin sodium equivalent to 200 mg clavulanic acid/1 g amoxicillin

Consumer Medicine Information

What is in this leaflet
This leaflet answers some common questions about AUGMENTIN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

Please read this leaflet before you start using AUGMENTIN. If you are helping someone else take AUGMENTIN, please read this leaflet before you give the first dose.

All medicines have risks and benefits. Your doctor has weighed the expected benefits against possible risks of you using AUGMENTIN. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What AUGMENTIN is used for

AUGMENTIN is an antibiotic used to treat infections in different parts of the body caused by bacteria.

AUGMENTIN will not work against infections caused by viruses such as colds or the flu.

AUGMENTIN is also used to prevent infection from major surgery.

AUGMENTIN is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

This medicine is available only with a doctor's prescription.

Do not take AUGMENTIN if:

- you have an allergy to AUGMENTIN, other penicillins or any of the ingredients listed at the end of this leaflet.
- you have had an allergic reaction to cephalosporins (another type of antibiotic). You may have an increased chance of being allergic to AUGMENTIN if you are allergic to cephalosporins.
- you have had liver disease or yellowing of the skin and/or eyes, also called jaundice when you have taken amoxicillin/clavulanic acid (or AUGMENTIN) before.
- the packaging is torn or shows signs of tampering, or the medicine has changed colour
- the expiry date (EXP) printed on the pack has passed.
  If you have used this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start using AUGMENTIN, contact your doctor.

Do not give this medicine to anyone else. Your doctor has prescribed it specifically for you and your condition.

Before you have AUGMENTIN

Tell your doctor if:

- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- you have glandular fever. If AUGMENTIN is used with glandular fever a rash may develop
- you have liver disease
your kidneys do not work as well as they should
you are on a salt-restricted diet
you are taking warfarin (Coumadin™, Marevan™) or other medicines used to prevent blood clots
you are passing less urine
you are pregnant or intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of using AUGMENTIN during pregnancy.
you are breastfeeding or wish to breastfeed. Your doctor will discuss with you the possible risks and benefits of using AUGMENTIN during breastfeeding.
you are taking any other medicines or herbal remedies.

AUGMENTIN is not addictive.

AUGMENTIN does not usually affect the ability to drive or operate machinery.

Taking other medicines with AUGMENTIN

Tell your doctor if you are taking:

- Probenecid, Allopurinol (Zyloprim™, Progout™; usually used for gout)
- Birth control pills (“the pill”, oral contraceptives). Birth control pills may not work as well in preventing pregnancy when AUGMENTIN is used. Talk to your doctor about the need for an additional method of contraception while using AUGMENTIN.
- Warfarin (Coumadin™, Marevan™) or other medicines used to prevent blood clots
- Mycophenolate mofetil, a medicine used to suppress your immune system.

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you which medicines are safe to take with AUGMENTIN.

How to use AUGMENTIN injection

Follow your doctor’s instructions about how and when to use AUGMENTIN.

Read the label carefully. If you have any concerns about how to use AUGMENTIN, talk to your doctor or pharmacist.

How much AUGMENTIN you should have

The usual dose is as follows, depending on the type of infection and how severe it is.

- Children 0-3 months: 30 mg/kg AUGMENTIN every 12 hours in infants < 4 kg and 30 mg/kg AUGMENTIN every 8 hours in infants >4 kg
- Children 3 months - 12 years: Usually 30 mg/kg AUGMENTIN 8 hourly.
- Adults and Children 40 kg and over: Usually 1.2 g 8 hourly.

- Dosage for surgical prophylaxis: Procedures in adults lasting for less than 1 hour - 1.2 g AUGMENTIN Intravenous. Longer operations require subsequent doses of 1.2 g AUGMENTIN IV (up to 4 doses in 24 hours).

How and when to use AUGMENTIN injection

Your doctor or nurse will make the AUGMENTIN injection up with sterile water and then give it by injection into the vein.

How long to use AUGMENTIN injection

AUGMENTIN injection may be given for one dose or a few doses or longer according to the doctor’s recommendation. Sometimes the doctor may then prescribe AUGMENTIN tablets to follow (see AUGMENTIN tablet CMI).

Keep using this medicine for the full time of treatment, even if you begin to feel better after a few days.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

AUGMENTIN is not usually used for longer than 14 days without another check-up by the doctor.

If you forget to have a dose of AUGMENTIN

If you miss a dose of AUGMENTIN take it as soon as you remember. If it is nearly time for your next dose
skip the dose you have missed and use the next dose as you are meant to. Do not use a double dose to make up for the dose you have missed. If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

It is important to use the injection as prescribed so it will work properly. If you have trouble remembering to have the doses ask your pharmacist for hints.

**If you have too much (Overdose)**

If you take too much AUGMENTIN you may get diarrhoea and nausea. If too many injections have been used or taken immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice. Do this even if there are no signs of discomfort or poisoning. Keep telephone numbers of these places handy.

**While you are using AUGMENTIN**

**Things you must do**

- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.
- If you develop itching with swelling or skin rash or difficulty breathing while you are using AUGMENTIN do not take any more and contact your doctor immediately.
- If you get severe diarrhoea or stomach cramps tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after AUGMENTIN has been stopped. Diarrhoea or stomach cramps may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.
- If you get a sore white mouth or tongue while using or soon after stopping AUGMENTIN, tell your doctor. Also tell your doctor if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush.
- If you become pregnant while you are using AUGMENTIN tell your doctor.
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking AUGMENTIN.
- If you have to have any blood tests tell your doctor you are using AUGMENTIN. AUGMENTIN may affect the results of some blood tests.
- Drink plenty of water, juice or other fluids (e.g. 6-8 glasses per day).
- Tell any doctor, dentist and pharmacist treating you that you are using AUGMENTIN.

**Things to be careful of**

- Do not stop having your injection because you are feeling better, unless advised by your doctor.
- If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.
- Do not give AUGMENTIN to anyone else, even if they have the same condition as you.
- Do not use AUGMENTIN to treat any other complaints unless your doctor tells you to.

**Side effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using AUGMENTIN.

Like other medicines, AUGMENTIN can cause some side effects. If they occur, they are most likely to be minor and temporary. However, rarely some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

**Mild Effects**
Tell your doctor if you notice any of the following that are troublesome or ongoing:

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- diarrhoea, nausea, vomiting or indigestion.

**More Serious Effects**

Tell your doctor immediately if you notice any of the following:

- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes (jaundice), and dark coloured urine. This may be a sign of liver disease. It may occur while using AUGMENTIN or even a few weeks after stopping AUGMENTIN.
- symptoms such as fever, severe chills, sore throat or mouth ulcers which can be a sign of lack of white blood cells
- rash – even if it starts a few days or more after starting AUGMENTIN
- itchy or burning skin – even if it starts a few days or more after starting AUGMENTIN

You may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with AUGMENTIN:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above

These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, this side effect is rare.

Do not take any diarrhoea medicine without first checking with your doctor.

**If any of the following happen, stop using AUGMENTIN and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:**

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects reported with AUGMENTIN include:

- seizures (very rare), dizziness, headache
- flu like symptoms wish 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)).

Some people may get other side effects while using AUGMENTIN.

Ask your doctor or pharmacist if you don’t understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

**After using AUGMENTIN**

**Storage**

Store AUGMENTIN injection vials containing powder in a cool dry place where the temperature stays below 25°C. Heat and dampness can destroy some medicines. Do not keep medicines in the bathroom or near a sink. Do not leave it in the car or on window sills.

Once the AUGMENTIN vial is made up with appropriate liquid it should be used within 3-4 hours depending on how it is made up.

Store all medicines out of the reach of children such as in a locked cupboard.
Disposal

If your doctor advises you to stop using AUGMENTIN or the medicine has passed its expiry date, ask your pharmacist what to do with any injection vials that are left over.

Product Description

What It Looks Like

AUGMENTIN injection comes as vials of sterile white to off-white powder. It is made up with sterile water before being injected.

Other Ingredients

AUGMENTIN injection only contains amoxicillin sodium and potassium clavulanate.

AUGMENTIN injection does not contain sucrose, lactose, gluten or tartrazine.

Further Information

AUGMENTIN injection is only available if prescribed by a doctor.

AUGMENTIN injection is available in packs of 10 vials.

Supplier

AUGMENTIN injection is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland
NEW ZEALAND

Phone: (09) 367 2900
Facsimile: (09) 367 2910

This leaflet was prepared on 23 November 2017.

Version 3.0

Trade marks are owned by or licensed to the GSK group of companies.

© 2017 GSK group of companies or its licensor.