

AUGMENTIN powder for oral suspension

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using AUGMENTIN?

AUGMENTIN contains the active ingredient potassium clavulanate/amoxicillin trihydrate. AUGMENTIN is used for the short term treatment of infections in different parts of the body caused by bacteria.

For more information, see Section [1. Why am I using AUGMENTIN?](#) in the full CMI.

2. What should I know before I use AUGMENTIN?

Do not use if you have ever had an allergic reaction to AUGMENTIN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use AUGMENTIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AUGMENTIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use AUGMENTIN?

- The usual dose may depend on the type of infection and how severe it is.

More instructions can be found in Section [4. How do I use AUGMENTIN?](#) in the full CMI.

5. What should I know while using AUGMENTIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse you visit that you are using AUGMENTIN.• Keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days.
Things you should not do	<ul style="list-style-type: none">• Stop taking AUGMENTIN because you are feeling better, unless advised by your doctor.• Give AUGMENTIN to anyone else, even if they have the same condition as you.• Use AUGMENTIN to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• AUGMENTIN does not usually affect the ability to drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Keep the bottle tightly closed between doses. AUGMENTIN should be used within 7 days of being made up at the pharmacy.• Store in a refrigerator - the temperature should be between 2°C to 8°C.

For more information, see Section [5. What should I know while using AUGMENTIN?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor if you notice any of the common side effects of oral thrush or vaginal thrush and serious side effects in particular nausea, chest pain, yellowing of skin, fever, rash or burning skin, abdominal cramps, diarrhoea etc.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

AUGMENTIN powder for oral suspension

Active ingredient(s): Potassium clavulanate/amoxicillin trihydrate equivalent to 31.25 mg clavulanic acid/125 mg amoxicillin
Potassium clavulanate/amoxicillin trihydrate equivalent to 62.5 mg clavulanic acid/250 mg amoxicillin

Consumer Medicine Information (CMI)

This leaflet provides important information about using AUGMENTIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AUGMENTIN.**

Where to find information in this leaflet:

- [1. Why am I using AUGMENTIN?](#)
- [2. What should I know before I use AUGMENTIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use AUGMENTIN?](#)
- [5. What should I know while using AUGMENTIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using AUGMENTIN?

AUGMENTIN contains the active ingredient potassium clavulanate/amoxicillin trihydrate equivalent to 31.25 mg clavulanic acid/125 mg amoxicillin.

Potassium clavulanate/amoxicillin trihydrate equivalent to 62.5 mg clavulanic acid/250 mg amoxicillin.

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.

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

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

AUGMENTIN is an antibiotic used for the short-term treatment of infections in different parts of the body caused by bacteria.

2. What should I know before I use AUGMENTIN?

Warnings

Do not use AUGMENTIN if:

- you have an allergy to AUGMENTIN, other penicillins or any of the ingredients listed at the end of this leaflet.
Some of the symptoms of an allergic reaction may include skin rash, itching, or difficulty breathing.
- 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 product has changed colour.

- the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.

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

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

Check with your doctor if you:

- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- you have phenylketonuria as AUGMENTIN contains aspartame
- 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 taking warfarin (Coumadin™, Marevan™) or other medicines used to prevent blood clots
- you are passing less urine
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss with you the possible risks and benefits of using AUGMENTIN during pregnancy.

Your doctor will discuss with you the possible risks and benefits of using AUGMENTIN during breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

- Probenecid, Allopurinol (used to treat 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 taking AUGMENTIN.
- Warfarin (Coumadin™, Marevan™) or other medicines used to prevent blood clots
- Mycophenolate mofetil, (used to suppress your immune system).

Methotrexate (used to treat conditions such as cancer and severe psoriasis)

Some medicines may interfere with AUGMENTIN and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AUGMENTIN.

4. How do I use AUGMENTIN?

How much to take / use

The usual doses are below. These may depend on the type of infection and how severe it is.

- Children 3-9 months: 1.25 mL of AUGMENTIN 125 three times a day.
- Children 9 months - 2 years: 2.5 mL of AUGMENTIN 125 three times a day.
- Children 2-6 years: 5 mL of AUGMENTIN 125 three times a day. In severe infections this may be increased to 10 mL AUGMENTIN 125 three times a day.
- Children 7-12 years: 5 mL of AUGMENTIN 250 three times daily. In severe infections this may be increased to 10 mL of AUGMENTIN 250 three times a day.

When to take / use AUGMENTIN

- Shake well before each dose, then make sure you measure the dose accurately. Your pharmacist will be able to recommend a good measure to use. Screw the lid back onto the bottle tightly after measuring the dose. Take AUGMENTIN at the start of a meal. This makes it less likely to cause stomach upset or discomfort.

How to long to use AUGMENTIN

- Keep taking 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 use AUGMENTIN

AUGMENTIN should be taken regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- If you are not sure whether to skip the dose, talk to your doctor or pharmacist.
- It is important to take AUGMENTIN as prescribed so it will work properly. If you have trouble remembering to take the doses, ask your pharmacists for hints.

If you use too much AUGMENTIN

If you think that you have taken too much AUGMENTIN you may get diarrhoea and nausea and need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 0800 or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using AUGMENTIN?

Things you should do

- Tell your doctor if the symptoms of your infection do not improve within a few days, or if they become worse.
- 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 taking 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 taking AUGMENTIN.

Call your doctor straight away if you:

- Develop itching with swelling or skin rash or difficulty breathing while you are taking AUGMENTIN do not take any more and contact your doctor immediately.
- 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.
- Get a sore white mouth or tongue while taking 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.
- Become pregnant while you are taking AUGMENTIN

Remind any doctor, dentist, pharmacist or nurse you visit that you are using AUGMENTIN.

Things you should not do

- Stop taking AUGMENTIN because you are feeling better, unless advised by your doctor.
- If you do not complete the full course prescribed by your doctor, all 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.
- Give AUGMENTIN to anyone else, even if they have the same condition as you.
- Use AUGMENTIN to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AUGMENTIN affects you.

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

Looking after your medicine

- Keep the bottle tightly closed between doses.
- AUGMENTIN should be used within 7 days of being made up at the pharmacy.
- Store in a refrigerator - the temperature should be between 2°C to 8°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Infections and infestations:</p> <ul style="list-style-type: none"> • oral thrush - white, furry, sore tongue and mouth. • change in colour of teeth (rare) – this usually just brushes off using a toothbrush. • change in colour of the tongue with a furry appearance (very rare). <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • diarrhoea, nausea, vomiting or indigestion. <p>Renal and urinary disorders:</p> <ul style="list-style-type: none"> • vaginal thrush - sore and itchy vagina and/or discharge. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction</p> <ul style="list-style-type: none"> • Signs of a serious allergic reaction called drug-induced enterocolitis syndrome; symptoms start with repetitive vomiting (1 to 4 hours after administration), and further symptoms can include stomach pain, abnormal drowsiness, diarrhoea, low blood pressure and can progress to shock. • Raised itchy 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 mouth (angiodema), which may cause difficulty in swallowing or breathing • Collapse • Chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome. <p>Liver problems</p> <ul style="list-style-type: none"> • itching, yellowing of the skin and eyes (jaundice), chest pain, and dark coloured urine. This may be a sign of liver disease. It may occur while taking AUGMENTIN or even a few weeks after stopping AUGMENTIN. <p>Immune system disorders</p> <ul style="list-style-type: none"> • symptoms such as fever, severe chills, sore throat or mouth ulcers which can be a sign of lack of white blood cells. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Skin and subcutaneous disorders</p> <p>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)).</p> <ul style="list-style-type: none"> • 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) string of pearls (linear IgA disease)– 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. <p>Nervous system disorders</p> <ul style="list-style-type: none"> • seizures (very rare), dizziness, headache. <p>Other side effects reported with AUGMENTIN include:</p> <ul style="list-style-type: none"> • 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 • chest pain. <p>Gastrointestinal disorders</p> <p>severe abdominal cramps or stomach cramps, water diarrhoea which may also be bloody, fever in combination of 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. Do not take any diarrhoea medicine without first checking with your doctor.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>If any of the following happen, stop taking AUGMENTIN and tell your doctor immediately or go to the accident and Emergency department at your nearest hospital:</p> <p>Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with AUGMENTIN:</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via <https://nzphvc.otago.ac.nz/reporting>.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

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7. Product details

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

What AUGMENTIN contains

Active ingredient (main ingredient)	Amoxicillin trihydrate Potassium clavulanate
Other ingredients (inactive ingredients)	Orange dry flavour 1 Orange dry flavour 2 Raspberry dry flavour NN07943 Golden syrup dry flavour 52927/AP, Xanthan gum Aspartame Succinic acid, Colloidal silicon dioxide Hypromellose Silicon dioxide
Potential allergens	AUGMENTIN does not contain sucrose, lactose, gluten or tartrazine.

Do not take this medicine if you are allergic to any of these ingredients.

What AUGMENTIN looks like

AUGMENTIN is white to off white in colour.

AUGMENTIN 125 powder for oral suspension 125 mg/31.25 mg/5 mL: TT50-3278/2a S

AUGMENTIN Forte powder for oral suspension 250 mg/62.5 mg/ 5 mL

Who distributes AUGMENTIN

GlaxoSmithKline NZ Ltd

Private Bag 106600

Downtown

Auckland 1143

New Zealand