

AUGMENTIN tablets

Consumer Medicine Information (CMI) summary

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

1. Why am I taking AUGMENTIN?

AUGMENTIN contains the active ingredients potassium clavulanate and 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 taking AUGMENTIN?](#) in the full CMI.

2. What should I know before I take AUGMENTIN?

Do not take 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 taking 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 take AUGMENTIN?

- The usual dose may depend on the type of infection and how severe it is.
- Take AUGMENTIN at the start of a meal to minimise any stomach upsets or discomforts.

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

5. What should I know while taking AUGMENTIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse you visit that you are taking AUGMENTIN.• Keep taking this medicine for the full course 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.
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 tablets in the blister pack until it is time to take them.• AUGMENTIN tablets should be used within 30 days of the foil pouch being opened.• Store in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking 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 the skin, fever, rash or burning skin, abdominal cramps, diarrhoea, tremors, swollen glands, bleeding and/or bruising more easily.

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 tablets

Active ingredients: potassium clavulanate and amoxicillin trihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about taking 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 taking AUGMENTIN.**

Where to find information in this leaflet:

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

1. Why am I taking AUGMENTIN?

AUGMENTIN contains the active ingredients potassium clavulanate and amoxicillin trihydrate.

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 is used for the short-term treatment of 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.

2. What should I know before I take AUGMENTIN?

Warnings

Do not take AUGMENTIN if:

- you are allergic to amoxicillin trihydrate or potassium clavulanate, other penicillin antibiotics or any of the ingredients listed at the end of this leaflet.
- you have had an allergic reaction to another type of antibiotic known as cephalosporins.
You may have an increased chance of being allergic to AUGMENTIN if you are allergic to cephalosporins.
- you have liver disease or yellowing of the skin and/or eyes (jaundice) when you have taken an antibiotic before.

Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- you have glandular fever.
If AUGMENTIN is taken when you have glandular fever a rash may develop.
- your kidneys do not work as well as they should.

- you are passing less urine than usual or are not able to drink very much.
- you are taking warfarin (Coumadin™, Marevan™) or other medicines used to prevent blood clots

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 taking AUGMENTIN during pregnancy or whilst 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.

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

- probenecid, allopurinol, medicines used to treat gout).
- oral contraceptive pills ("birth control pills").
AUGMENTIN may reduce how well the contraceptive pill whilst you're being treated with AUGMENTIN, you should also use a barrier method of contraception (such as condoms). Talk to your doctor for advice.
- warfarin (Coumadin™, Marevan™) or other medicines used to prevent blood clots
- mycophenolate mofetil a medicine used to prevent the rejection of transplanted organs or to suppress your immune system.
- methotrexate, a medicine used to treat conditions such as cancer and severe psoriasis.

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 take AUGMENTIN?

How much to take

- the usual dose for adults and children 40 kg and over is one tablet twice a day or one to two tablets three times a day, depending on the type of infection and how severe it is.

- follow the instructions provided when AUGMENTIN was prescribed including the number of days it should be taken.

When to take AUGMENTIN

- swallow the tablets whole with a glass of water.
- take AUGMENTIN at the start of a meal. This makes it less likely to cause stomach upset or discomfort.

How to long to take AUGMENTIN

- keep taking this medicine for the full course 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 your doctor.

If you forget to take 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 take too much AUGMENTIN

If you think that you have taken too much AUGMENTIN, you may need urgent medical attention. The most common side effects of taking too much AUGMENTIN are nausea, vomiting and diarrhoea.

You should immediately:

- phone the Poisons Information Centre (**by calling 0800 POISON or 0800 764 766**), or
- contact your doctor or pharmacist, 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 taking 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 need to have a blood test, 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 to 8 glasses per day).

Remind any doctor, dentist or pharmacist you visit 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 and stop taking AUGMENTIN.
- get severe diarrhoea or stomach cramps. Do this even if it occurs several weeks after you have finished taking AUGMENTIN. 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.
- develop symptoms such as tremors, a confused state, yellowing of skin and/or eyes, swollen glands and bleeding or bruising more easily. These symptoms can be related to a rare serious immune system condition called haemophagocytic lymphohistiocytosis/macrophage syndrome.
- get a sore white mouth or tongue while taking or soon after stopping AUGMENTIN. Also tell your doctor if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush.

Things you should not do

- do not stop taking AUGMENTIN because you are feeling better, unless advised by your doctor.

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 tablets in the blister pack until it is time to take them.
- AUGMENTIN tablets should be used within 30 days of the foil pouch being opened.
- store in a cool dry place where the temperature stays below 25°C.

Follow the instructions on 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 tablets that are left over.

Getting rid of any unwanted medicine

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

Do not take 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>Haemophagocytic lymphohistiocytosis/macrophage syndrome</p> <ul style="list-style-type: none"> fever. skin rashes. problems related to nerves, such as shaking or tremor, confusional state. upper abdominal pain. yellowing of the skin and/or eyes. swollen glands in the neck, armpit and/or groin. bleeding and/or bruising more easily; looking pale, feeling tired. 	<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>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>Skin and subcutaneous disorders</p> <ul style="list-style-type: none"> flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)). symmetrical drug related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome). 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>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>

Serious side effects	What to do
<p>Gastrointestinal disorders</p> <ul style="list-style-type: none"> 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. <p>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>

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://pophealth.my.site.com/carmreportnz/s/>

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

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

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)	colloidal silicon dioxide dimethicone hypromellose macrogol 4000 macrogol 6000 magnesium Stearate microcrystalline cellulose Opadry white OY-S-7300 (as an alternative source of film coating) sodium starch glycollate titanium dioxide

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

What AUGMENTIN looks like

AUGMENTIN tablets are white to off white, oval shaped, film coated tablets, engraved 'AC' with a score line on one side and plain on the other side (TT50-3278).

AUGMENTIN is available in packs of 10. Foil pouches may contain a sachet (desiccant) to keep the tablets dry. Do not eat this sachet

Who distributes AUGMENTIN

GlaxoSmithKline NZ Ltd
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Downtown
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