

AUGMENTIN powder for oral suspension

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

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 taking 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 taking this medicine, ask your doctor or pharmacist.

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

What is AUGMENTIN used for?

AUGMENTIN is an antibiotic 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.

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.

Before you take AUGMENTIN

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. Some of the symptoms of an allergic reaction may include skin rash, itching, 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.

Before you start to take 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 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 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 taking 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 take AUGMENTIN

Follow your doctor's instructions about how and when to take AUGMENTIN.

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

How much to take

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.

How and when to take 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 long to take 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 take a dose of AUGMENTIN

If you forget to take 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 take the next dose as you are meant to. Do not take a double dose to make up for the dose you have missed. Try and remember to take it at the start of a meal.

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 pharmacist for hints.

If you take too much (Overdose)

If you take too much AUGMENTIN you may get diarrhoea and nausea. If too much has been 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 taking 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 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.
- If you become pregnant while you are taking 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 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.

Things to be careful of

- Do not 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 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 taking 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 taking 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.

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

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:

- 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.

- 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)
- 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)).

Some people may get other side effects while taking 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 taking AUGMENTIN

Storage

Store in a refrigerator - the temperature should be between 2°C to 8°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.

Keep the bottle tightly closed between doses. AUGMENTIN should be used within 7 days of being made up at the pharmacy.

Store all medicines out of the reach of children.

Disposal

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.

Product Description

What It Looks Like

AUGMENTIN is white to off white in colour.

Other 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.

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

Further Information

AUGMENTIN is only available if prescribed by a doctor.

AUGMENTIN is available in 100 mL bottles.

Supplier

Augmentin is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland
NEW ZEALAND

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

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