

AUGMENTIN TABLET

Amoxicillin trihydrate/ Potassium clavulanate (500 mg/125 mg, 875 mg/125 mg)

What is in this leaflet

1. What Augmentin is used for
2. How Augmentin works
3. Before you use Augmentin
4. How to use Augmentin
5. While you are using it
6. Side Effects
7. Storage and Disposal of Augmentin
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Augmentin is used for

Augmentin is used in adults and children to treat the following infections:

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections.

How Augmentin works

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.

Before you use Augmentin

- When you must not use it

Do not take Augmentin:

- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of Augmentin
- 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 applies to you. If you are not sure, talk to your doctor or pharmacist before taking Augmentin.

- Before you start to use it

Talk to your doctor or pharmacist before taking this medicine if you:

- have glandular fever (viral infection that normally transmitted through saliva and causes sore throat, swollen glands and fever)
- are being treated for liver or kidney problems
- are not passing water regularly.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist 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.

If you are pregnant, you think you might be pregnant or if you are breast-feeding, please tell your doctor or pharmacist.

Ask your doctor or pharmacist for advice before taking any medicine.

- Taking other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that can be bought without a prescription and herbal medicines. Please inform your doctor if you are taking:

- Allopurinol, Probenecid (used for gout).
- Medicines used to help stop blood clots (such as warfarin).
- Mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs).
- Contraceptive pill, as with other antibiotics, you may need to use extra birth control methods (e.g. condoms) while taking Augmentin.

How to use Augmentin

- How much to use

Always take Augmentin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and children over 12 years

Mild – Moderate infections: one Augmentin 625 mg tablet twice daily

Severe infections: one Augmentin 1 g tablet twice daily
Therapy can be started parenterally and continued with an oral preparation.

Dosage in dental infections (e.g. dentoalveolar abscess)

Adults and children over 12 years: one Augmentin 625 mg tablet 2 times a day for five days

Augmentin 625 mg and 1 g tablets are not recommended in children of 12 years and under

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed.
- If you have liver problems, you may have more frequent blood tests to see how your liver is working.

How to take Augmentin

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before. Tablets can be broken along the score line to make them easier to swallow. You must take both pieces of the tablet at the same time.
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Keep taking Augmentin until the treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

- Do not take Augmentin for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember. You should not take the next dose too soon, but wait about 4 hours before taking the next dose.

- If you use too much (overdose)

If you have too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible. Take the medicine carton or bottle to show the doctor.

While you are using it

- Things you must do

Always take Augmentin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Things you must not do

This medicine has been prescribed for you (or for your child). Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

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.

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 type of tests.

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.

Side Effects

Like all medicines, Augmentin can cause side effects, although not everybody gets them. Conditions you need to look out for:

Very common side effects

These may affect more than 1 in 10 people

- diarrhoea (in adults).

Common side effects

These may affect up to 1 in 10 people

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses. If affected take Augmentin before food
- vomiting
- diarrhoea (in children).

Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised itchy rash (hives)
- 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.

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

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown

- 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 mouth (*angioedema*), causing difficulty in breathing
 - Contact a doctor immediately if you get any of these symptoms. Stop taking Augmentin.
- 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.
- 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*)

Contact 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
- Hyperactivity
- Convulsions (in people taking high doses of Augmentin or who have kidney problems)
- Black tongue which looks hairy

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

If you get side effects, tell your doctor or pharmacist if any of the side effects become severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Augmentin

- Storage

Keep out of the reach and sight of children.
Augmentin should be stored in a dry place at 25°C or below.

Bottles of Augmentin Tablets should be kept tightly closed and the tablets dispensed in moisture-proof containers. Do not use Augmentin after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Tablets supplied in pouches should be used within 30 days of opening the pouch.

Store in the original pack in order to protect from moisture. Do not use if the tablets are chipped or there are other visible signs of deterioration.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Augmentin tablet 625 mg: A white to off white oval shaped, film coated debossed with 'AC' and a score line on one side and plain on the other side.

Augmentin tablet 1 g: White oval film-coated tablets engraved with 'AC' either side of a break line on one side and A C only on the other side.

- Ingredients

- Active ingredient(s)
Amoxicillin trihydrate and potassium clavulanate

- Inactive ingredient(s)
Colloidal silicon dioxide, sodium starch glycolate, magnesium stearate (E572), microcrystalline cellulose, titanium dioxide (E171), hydroxypropyl methylcellulose,

polyethylene glycol,
dimethicone (silicon oil).

- MAL number

Augmentin Tablet 625 mg
MAL19986474ARZ

Augmentin Tablet 1 g
MAL19972945ARZ

Manufacturer

SmithKline Beecham Limited
Clarendon Road Worthing,
West Sussex, BN 148QH,
United Kingdom

Product Registration Holder

GlaxoSmithKline
Pharmaceutical Sdn. Bhd.
Level 6, Quill 9,
112 Jalan Semangat,
46300 Petaling Jaya,
Selangor, Malaysia

Date of Revision

12/07/2017

Serial Number:

BPFK(R4/1)30062017/00163