

AUGMENTIN TABLET

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

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What Augmentin is used for

Augmentin is an antibiotic 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, other penicillin based antibiotics, or similar antibiotics called cephalosporins. if you have

ever had liver problems or jaundice (yellowing of the skin and/or whites of the eyes) 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 ever had an allergic reaction to any other antibiotics or medicines. This might include a skin rash or swelling of the face or neck
- have glandular fever (mononucleosis - viral infection that normally transmitted through saliva and causes sore throat, swollen glands and fever)
- are taking medicines, such as warfarin, that are used to prevent blood clots
- have liver problems
- you have kidney disease
- are not urinating regularly or not able to drink very much
- have a genetic condition called phenylketonuria

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. Augmentin can also affect how some other medicines work. Please inform your doctor if you are taking:

- Allopurinol, Probenecid (used for gout).
- Anticoagulants - medicines used to prevent blood clots (such as warfarin and acenocoumarol).
- Mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs).
- methotrexate (used to treat conditions such as cancer and severe psoriasis).
- 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 or one Augmentin 625mg tablet three times daily. Therapy can

be started parenterally and

continued with an oral preparation.

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.

- 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 14 days. 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

Don't take a double dose to make up for a missed dose. Just take it as soon as you remember.

If you are not sure what to do, ask your doctor or pharmacist.

- If you use too much (overdose)

If you accidentally take too much Augmentin, it is unlikely to cause any serious problems.

The most common side effects of taking too much Augmentin are nausea, vomiting and diarrhea. If you are worried, or you feel unwell, ask your doctor or pharmacist for advice.

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, chest pain, repetitive vomiting within 1 to 4 hours of Augmentin administration, 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.

Augmentin may cause severe allergy and serious skin reactions. Stop using Augmentin and seek medical assistance immediately if you experience any of the following symptoms:

- skin reddening, blisters, rash, fever, sore throat or eye irritation.

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 (fungal infection caused by *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
- itchy, bumpy 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*)

Rare side effects that may show up in your blood tests:

- decrease in the number of cells that help blood to clot (*thrombocytopenia*)
- decrease in the number of white blood cells (*leucopenia*, including *neutropenia*)

Very rare side effects

These may affect up to 1 in 10,000 people:

- severe allergic reactions
 - raised, itchy rash (hives)
 - 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*), 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*.
 - repetitive vomiting (1 to 4 hours after Augmentin administration), stomach pain, abnormal drowsiness, diarrhoea and low blood pressure which can be a sign of a serious allergic reaction called drug-induced enterocolitis syndrome.
 - 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: These are rare in people taking Augmentin. Signs include:

- 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*)

These are very rare in people taking Augmentin. Stop taking Augmentin and contact your doctor immediately if you experience any of the following:

- 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 blisters and peeling skin on much of the body surface (*toxic epidermal necrolysis*).
- a red, itchy, scaly rash with blisters and bumps under the skin (*bullous exfoliative dermatitis*)
- A widespread, red, skin rash with small blisters containing pus (*exanthemous pustulosis*)
- serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes.
- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck (*Symmetrical Drug-*

related Intertriginous and Flexural Exanthema (SDRIFE)).

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
- Inflammation of the protective membrane surrounding the brain (aseptic meningitis)

Not known side effects

- rash with blisters arranged in a circle with central crusting or like a string of pearls (*linear IgA disease*).

Side effects that may show up in your blood or urine tests:

- Severe reduction in the number of white blood cells (*agranulocytosis*)
- 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 or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my
[Consumers → Reporting Side

Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Augmentin

- Storage

Keep out of the reach and sight of children.

Tablets which are available in desiccated blister pouch packs contains desiccant sachet, do not remove or eat.

Do not store the open blister pouch above 30°C. Throw away any unused tablets 14 days after first opening.

Store in a dry place in the original packaging to protect from moisture.

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.

- Disposal

Don't dispose of medicines in waste water or household waste. Ask your pharmacist

how to dispose of medicines no longer required. This 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 tablet, debossed with 'AC' and a score line on one side and plain on the other side.

Augmentin tablet 1 g: A white to off-white capsule-shaped, film-coated tablet, debossed with 'AC' on both sides and a score line on one 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 1g
MAL19972945ARZ

Manufacturer

SmithKline Beecham Limited
Worthing, UK

Product Registration Holder

GlaxoSmithKline Pharmaceutical Sdn. Bhd.
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