

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

AUGMENTIN 500 MG/125 MG TABLETS

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What Augmentin is and what it is used for
2. Before you take/use Augmentin
3. How to take/use Augmentin
4. Possible side effects
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1. WHAT AUGMENTIN IS AND WHAT IT IS USED FOR

Augmentin is an antibiotic used in adults and children to treat infections in different parts of the body caused by certain types of bacteria.

Augmentin contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin is a penicillin antibiotic. Amoxicillin can sometimes be stopped from working (made inactive). The other active medicine, clavulanic acid, stops this from happening.

2. BEFORE YOU TAKE AUGMENTIN

Don't take Augmentin

- if you're 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.
- if you think any of these apply to you, check with your doctor before you take Augmentin.

Take special care with AUGMENTIN

Before you take Augmentin, your doctor needs to know:

- 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.
- if you have **glandular fever (mononucleosis)**
- if you're taking medicines, such as warfarin, that are used to **prevent blood clots**
- If you have **liver problems**
- if you have **kidney disease**
- if you're not **urinating regularly** or not able to **drink** very much.
- if you have a genetic condition called phenylketonuria

→ **Check with your doctor** if you think any of these may apply to you. Your doctor will decide whether Augmentin is suitable for you and may need to adjust your dose or give you a different medicine.

Look out for important symptoms

Augmentin can make some existing conditions worse, or cause serious side effects, such as severe allergic reactions, serious skin reactions, serious liver problems or severe diarrhoea or inflammation of the large intestines (pseudomembranous colitis). You must look out for certain symptoms while you're taking Augmentin to help reduce the risk of any problems.

Taking other medicines

Other medicines and Augmentin:

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.

Some medicines may affect how Augmentin works, or make it more likely that you'll have side effects. These include:

- **probenecid** and **allopurinol** (used to **treat gout**).
- **anticoagulants** (used to **prevent blood clots**) such as warfarin and acenocoumarol.
- **mycophenolate mofetil** (a medicine used to **prevent the rejection of transplanted organs**).

→ Tell your doctor or pharmacist if you're taking any of these.

Augmentin may reduce how well the **contraceptive pill** works. If you're taking the contraceptive pill while you're being treated with Augmentin, you should also use a **barrier method of contraception** (such as condoms). Ask your doctor for advice.

Pregnancy and breast-feeding

If you're **pregnant**, or **think you could be**, or if **you're planning to become pregnant**, **don't take Augmentin** without checking with your doctor. Your doctor will consider the benefit to you and the risk to your baby of taking Augmentin while you're pregnant.

You can usually breast-feed while you're taking Augmentin. If you're breast-feeding or considering breast-feeding, **check with your doctor before you take Augmentin**.

Augmentin suspension contains **aspartame**, which is a source of phenylalanine. If you have an intolerance to aspartame or have a condition called **phenylketonuria (PKU)**:

→ Check with your doctor that Augmentin suspension is right for you.

3. HOW TO TAKE AUGMENTIN

Always take Augmentin exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you're not sure.

How much to take

Your doctor will decide on the correct dosage for you

Patients with kidney or liver problems

- If you have kidney problems, your doctor may give you a different strength or a different medicine.
- If you have liver problems, you may have more frequent blood tests to check how your liver is working.

How to take

- Take Augmentin at the start of a meal or slightly before.
- Swallow the tablets whole with a glass of water.

Do not take Augmentin for more than 14 days. If you still feel unwell you should go back to **see your doctor**.

If you forget to take Augmentin

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

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

If you take too much Augmentin

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 diarrhoea. If you're worried, or you feel unwell:

→ Ask your doctor or pharmacist for advice.

Don't stop taking Augmentin without advice

It is important that you take the full course of Augmentin. Don't stop unless your doctor advises you to – even if you're feeling better. If you don't complete the full course of treatment, the infection may come back.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Augmentin can cause side effects, although not everybody gets them.

Look out for important symptoms

Severe allergic reactions

These are very rare in people taking Augmentin. Signs include:

- 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.

→ **Get medical help immediately** if you get any of these symptoms. Stop taking Augmentin.

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. Signs include:

- 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 widespread, red, skin rash with small blisters containing pus (exanthemous pustulosis)
- a red, itchy, scaly rash with blisters and bumps under the skin (bullous exfoliative dermatitis)
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

→ Get medical help immediately if you get any of these symptoms. Stop taking Augmentin.

Serious liver problems

On rare occasions, medicines like Augmentin can cause liver problems, causing yellowing of the skin and/or whites of the eyes.

→ Tell your doctor as soon as possible if you get any of these symptoms.

Severe diarrhoea (Pseudomembranous colitis)

On rare occasions, medicines like can cause inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain and fever.

→ Tell your doctor as soon as possible if you get any of these symptoms.

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 in the vagina, mouth or skin folds)
- feeling sick (nausea)
- vomiting
- diarrhoea (in children).

Uncommon side effects

These may affect up to 1 in 100 people:

- dizziness
- headache
- indigestion
- skin rash
- itching
- itchy, bumpy rash (hives)

Uncommon side effects that may show up in blood tests are:

- increase in some substances (enzymes) produced by the liver

Rare side effects

These may affect up to 1 in 1,000 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) (See ‘serious skin reactions’ earlier in Section 4)

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

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

Very rare side effects

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

- severe allergic reactions (See also ‘severe allergic reactions’ earlier in Section 4)
- serious skin reactions (See also ‘serious skin reactions’ earlier in Section 4)
- inflammation of the liver (hepatitis) (See also ‘serious liver problems’ earlier in Section 4)
- yellowing of the whites of the eyes or skin (jaundice) (See also ‘serious liver problems’ earlier in Section 4)
- inflammation of the large intestines (See also ‘severe diarrhoea’ earlier in Section 4)
- inflammation of the kidney (nephritis)
- an increase in the time blood takes to clot
- being unusually active (hyperactivity)
- fits (seizures)

- black tongue which looks hairy
- inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- stained teeth that can usually be removed by brushing (from the oral suspension formulations)

Very rare side effects that may show up in blood or urine tests are:

- severe decrease in the number of white blood cells (agranulocytosis)
- red blood cells destroyed too quickly (haemolytic anaemia)
- crystals in urine

→ Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE AUGMENTIN

Keep out of the sight and reach of children.

Do not take Augmentin after the expiry date shown on the pack.

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

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.

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.

6. FURTHER INFORMATION

The active substances are amoxicillin and clavulanic acid.

Augmentin tablets come in different strengths.

What Augmentin contains:

Each tablet contains either:

Amoxicillin trihydrate equivalent to 500 mg amoxicillin
 Potassium clavulanate equivalent to 125 mg clavulanic acid
 Colloidal silicon dioxide
 Sodium starch glycolate
 Magnesium stearate (E572)
 Microcrystalline cellulose
 Titanium dioxide (E171)
 Hydroxypropyl methylcellulose
 Polyethylene glycol
 Dimethicone (silicon oil).

What Augmentin looks like and contents of the pack:

Augmentin 625 mg tablets are available in a carton containing blister foil pack. Each blister pack is stored within a sealed pouch, with a desiccant sachet. The tablets are a white to off-white oval-shaped film-coated debossed tablet, with a score line on one side and plain on the other side.

Manufacturer

Smithkline Beecham Ltd, Clarenadon Road, Worthing, West Sussex, BN14 8HQ, United Kingdom.

This leaflet was last approved on

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