1. WHAT AUGMENTIN IS AND WHAT IT IS USED FOR

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

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AUGMENTIN

If you have any further questions on the use of this medicine, ask your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Augmentin is and what it is used for
2. What you need to know before you take Augmentin
3. How to take Augmentin
4. Possible side effects
5. How to store Augmentin
6. Contents of the pack and other information

3. HOW TO TAKE AUGMENTIN

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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Inflammation of large intestine
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.
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:
• thirst (candida - a yeast infection of the vagina, mouth or skin folds)
• feeling sick (nausea), especially when taking high doses
• if affected take Augmentin with a meal
• 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.

Rare side effects that may show up in your blood tests:
• low number of red blood cells
• low number of white blood cells
• low number of platelets.

Frequency not known
Frequency cannot be estimated from the available data.

Allergic reactions (see above)
• Inflammation of the large intestine (see above)
• Inflammation of the protective membrane surrounding the brain (aseptic meningitis)
• Serious skin reactions:
  • a widespread red 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 red pus-containing blisters (bullous exfoliative dermatitis)
  • a red, scaly rash with bumps under the skin and blisters (seamannah pejus/latusee)
  • Rash with symptoms of 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)).
• Contact a 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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yell or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

HOW TO STORE AUGMENTIN
Do not store above 25°C. Store in the original package in order to protect from moisture.

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package in order to protect from moisture.

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Do not use any medicines after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture.

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Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

If your medicine become discoloured or show signs of any deterioration, consult your doctor or pharmacist who will tell you what to do.

CONTENTS OF THE PACK AND OTHER INFORMATION
The active substances are amoxicillin and clavulanic acid. Each tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin with potassium clavulanate equivalent to 125 mg clavulanic acid.

The other ingredients are:
• Tablets core - magnesium stearate, sodium starch glycollate (Type A), colloidal anhydrous silica, microcrystalline cellulose.
• Film-coat - titanium dioxide (E171), hypromellose, macrogol 4000, macrogol 6000 and silicone oil.

What Augmentin looks like and contents of the pack
Augmentin tablets are white to off-white, oval shaped, film-coated tablets, debossed ‘A’ breakline ‘C’ on one side and plain on the reverse.

They are available in blister pack containing 16 tablets.

PL: 15814/1228

Produced by SmithKline Beecham Pharmaceuticals, Worthing, UK OR Glaxo Welcome Production, Mayenne, France. Procured from within the EU and repackaged by the Product Licence Holder: O.P.D. Laboratories Ltd., Unit 6 Colonial Way, Watford, Herts WD24 4PR.

Leaflet revision and issue date (Ref.): 28.06.2018.

Augmentin is a trademark of GSK group of companies.
These tablets are not suitable for children weighing less than 25 kg.

Keep taking Co-amoxiclav Tablets 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.

6. Contents of the pack and other information

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-amoxiclav Tablets.

3. How to store Co-amoxiclav Tablets

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If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-amoxiclav Tablets.

If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), Co-amoxiclav Tablets 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 Co-amoxiclav Tablets, to reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

Warnings and precautions

If you have too much Co-amoxiclav Tablets, signs might include an upset stomach (feeling sick, being sick or vomiting) while you are taking Co-amoxiclav Tablets, to reduce the risk of any problems. See section 4.

Other medicines and Co-amoxiclav Tablets

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy, breast-feeding and fertility

If you are breast-feeding, it is important to talk to your doctor or pharmacist before taking Co-amoxiclav Tablets. It is not known whether Co-amoxiclav Tablets enter your breast milk. Before taking any new medicine, it is important that you discuss it with your doctor or pharmacist. They will weigh up the risks of taking this medicine against the possible benefits it might have for you.

If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Co-amoxiclav Tablets. This is because Co-amoxiclav Tablets can affect the results of these types of tests.

Other medicines and Co-amoxiclav Tablets

If you stop taking Co-amoxiclav Tablets

If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), Co-amoxiclav Tablets 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 Co-amoxiclav Tablets, to reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

Possible side effects

These tablets are not suitable for children weighing less than 25 kg.

If you forget any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

CO-AMOXICLAV 500 mg/125 mg FILM-COATED TABLETS

CO-AMOXICLAV (amoxicillin and clavulanic acid)
Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

What Co-amoxiclav Tablets looks like and contents of the pack

The active substances are amoxicillin and clavulanic acid. Each tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin with potassium clavulanate equivalent to 125 mg clavulanic acid.

What Co-amoxiclav Tablets contains

- The active substances are amoxicillin and clavulanic acid. Each tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin with potassium clavulanate equivalent to 125 mg clavulanic acid.
- The other ingredients are:

   - Tablet core - magnesium stearate, sodium starch glycolate (Type A), colloidal anhydrous silica, microcrystalline cellulose.
   - Dye st.
   - Titanium dioxide (E171), hypromellose, macrogol 4000, macrogol 6000 and silicone oil.

Co-amoxiclav Tablets are white to off-white, oval shaped, film-coated tablets, debossed 'A' breakline 'C' on one side and plain on the reverse.

Common side effects

These may affect up to 1 in 10 people
- skin rash, itching
- raised itchy rash (hives)
- indigestion
- dizziness
- headaches

Uncommon side effects

These may affect up to 1 in 100 people
- skin rash, itching
- raised itchy rash (hives)
- indigestion
- dizziness
- headaches

Very common side effects

These may affect more than 1 in 10 people
- swelling of the face, lips, mouth, throat, or tongue
- vomiting
- diarrhoea (in children)

Common side effects

These may affect up to 1 in 10 people
- skin rash, which may blister, and looks like small target(s) (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.

Side effects that may show up in your blood tests:
- increase in some substances (enzymes) produced by the liver.

Reporting of side effects

You can also report side effects directly via the Yellow Card Scheme at:

- 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)).

Contact a doctor immediately if you get any of these symptoms.
- Inflammation of the liver (hepatitis)
- jaundice, caused by increased blood level 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
- Red blood cell activity
- convulsions (in people taking high doses of Co-amoxiclav Tablets 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 any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

- a red, scaly rash with raised blisters (shampoo pustulosis)
- 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)).

Advice/medical education

1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. The remainder to a pharmacy for appropriate disposal.

2. You should not give antibiotics that were prescribed for you to other people.

3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.

4. You should not give antibiotics to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take

6. You should not give antibiotics that were prescribed for you to other people.

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To request a copy of this leaflet in Braille, large print or audio please call 01923 323 796.

Advice/medical education

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses. Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the environment in which resistant bacteria that are similar to the antibiotic working.

1. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.

2. You should not be given antibiotics that were prescribed for other people even if they had an infection that was similar to yours.

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