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Formulation
Tablet embossing
Storage conditions
Shelf Life

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Augmentin 1 gm film-coated Tablets Amoxicillin trihydrate and Potassium clavulanate

Information for the patients

Read this patient information leaflet carefully before taking or using this medicine. This medicine has been prescribed for you personally and you are not allowed to give it on to other persons. Even if these persons suffer from same symptoms as you, the medicine could be harmful for them. Keep the patient information leaflet, as you may need to read it again later.

What Augmentin is and what it is used for?

Augmentin is an antibiotic from the group of penicillins. It consists of two active ingredients: Clavulanic acid and Amoxicillin. Clavulanic acid dominates the main immunity or resistance mechanism of numerous resistant bacteria against penicillins and in this way it protects Amoxicillin, which can thus destroy the bacteria. This effectiveness makes Augmentin effective against numerous bacterial infections.

Augmentin should only be used with a prescription from your doctor only for treatment of the following bacterial infections:

- nose, throat, tonsil, front / maxillary sinus and ear infections;
- respiratory tract infections (bronchi and lungs);
- kidney, bladder and urinary tract infections;
- infections of the genital organs (gonorrhea, mucous discharge);
- gynecological infections;
- Skin and soft tissue infections (boils, abscesses, etc.).

What precautions should be taken into consideration?

Your doctor has prescribed this medicine in order to treat your current illness.

The antibiotic which exist in Augmentin is not effective against all microorganisms that cause infectious diseases. Using an incorrectly chosen or incorrectly dosed antibiotic can cause other complications. Therefore, never use it by yourself for the treatment of other diseases or other people. Even if the infections happen later once again, you are not allowed to use Augmentin without a new medical consultation. The symptoms of the disease often disappear before the infection has completely healed. Therefore, the treatment should not be stopped early, even if you feel better. Depending on the circumstances and according to the doctor's prescription, the treatment may last for two weeks or may even be longer.

When should not you use Augmentin?

You should not use Augmentin if you have previously had an allergic reaction to Augmentin, penicillins or cephalosporins. An allergy or hypersensitivity manifests itself, for example, in symptoms such as red spots on skin, fever, asthma, shortness of breath, circulatory problems, swelling of the skin (e.g. nettle fever) and mucous membranes, skin rashes or a painful tongue.

Augmentin should not be used if you are known or suspected to be hypersensitive to any of the other ingredients used in the medicine.

You must not take Augmentin if you have Pfeiffer's glandular fever or lymphoblastic leukemia.

When should you take caution while using Augmentin?

This medicine may affect your ability to react, drive and use tools or machines.

If you are taking an oral contraceptive (pill), there is a possibility that its effectiveness may be reduced during the therapy with the antibiotic. This note also applies to Augmentin. Therefore, your doctor or pharmacist can recommend further contraceptive measures. Indigestion is possible when taking Augmentin. In the event of severe gastrointestinal disorders with vomiting and diarrhea, the medication should be discontinued and the doctor should be informed immediately. This could be a case of drug-induced enterocolitis syndrome (see section "What side effects can Augmentin cause?"). He or she should also be notified if a rash or itching occurs. If diarrhea occurs, no drugs that inhibit bowel peristalsis (bowel movement) should be taken.

Individual cases of particularly serious allergic reactions, such as the (possibly life-threatening) have been described after taking Augmentin. Signs of such skin reactions are:

- Flu-like symptoms with rash and fever,
- Skin rash,
- reactions of the mucous membranes (e.g. swelling of the mucous membranes of the mouth or throat, blistering, bleeding).
- swelling of the face or other parts of the body.
- Pain in the chest (Kounis syndrome).

If you experience such symptoms after taking Augmentin, you must stop the treatment and contact a doctor immediately! If you suffer from allergies, allergic asthma, hay fever or nettle fever, special care should be taken when taking Augmentin because of possible hypersensitivity.

Patients who have to take allopurinol-containing preparations (like Zyloric) at the same time are more prone to rashes.

Inform your doctor if you have kidney illness; he or she will then prescribe a dosage tailored to your needs, which may differ from the table below in the "Usual Dosage" section.

Inform your doctor if you are taking anticoagulant agent (anticoagulants). Inform your doctor if you are taking any preparations containing mycophenolate mofetil that are used after organ transplantation to prevent acute graft rejection reactions.

If you are taking preparations containing digoxin, you must inform your doctor or pharmacist.

Penicillins can reduce the excretion of methotrexate (used to treat inflammatory joint diseases, cancer and severe psoriasis), which can lead to a possible increase in side effects.

If kidney or liver function is insufficient, special caution is advised. Inform your doctor or pharmacist if you:

- suffer from other diseases,
- Have allergies or
- take other medicines (including those you have bought yourself) or use other medicines externally

Can Augmentin be used during pregnancy or while breastfeeding?

Pregnancy

The decision of taking any kind of medication during pregnancy should be taken with extreme caution and only after consulting your doctor or pharmacist. Studies about pregnant women with premature rupture of the foetal membrane (pPROM), have reported that preventive treatment with Augmentin may cause an increased risk of sometimes serious tissue-damaging intestinal inflammation in the newborn.

Lactation

Since Augmentin is excreted in breast milk in small amounts, the possibility of a hypersensitivity reaction (with symptoms such as reddening of the skin and fever) or diarrhea is to be expected in infants. Therefore, Augmentin should not be taken while breastfeeding. Be sure to inform your doctor or pharmacist if you are pregnant, planning to become pregnant, or if you are breastfeeding. They are the only ones who can decide whether you can take Augmentin during these times.

How do you use Augmentin?

Usual dosage

Augmentin should preferably be taken with at least half a glass of water at the start of meals. This ensures an optimal effect and tolerance. Unless otherwise prescribed by the doctor, the following dosage applies:

For adults

Mild, moderate to severe infections:

- 2x daily Augmentin 1 gm (875/125)

The break groove of the 1 gm film-coated tablet is only intended to simplify tablet taking. The tablets are not intended to halve the dosage. Both halves must be taken at the same time.

Antibiotic therapy that has been started should be carried out for as long as prescribed by the doctor.

The symptoms of disease often disappear before the infection has completely healed. For this reason, do not stop therapy early, even if you feel much better.

Do not change the prescribed dosage on your own. If you think the medicine is too weak or too strong, consult your doctor or pharmacist.

Which side effects may occur while using Augmentin?

The following side effects have also been reported during treatment with Augmentin:

Very common (affects more than one in 10 people treated) :

Diarrhea, loose stools.

Common (affects 1 to 10 out of 100 people treated): Fungal infections of the skin/mucous membranes, abdominal pain, nausea, vomiting, allergic reactions, as with all medicines in the penicillin group

Occasionally (affects 1 to 10 out of 1000 people treated):

Gastrointestinal disorders such as stomach complaints or loss of appetite, flatulence, dyspepsia, altered liver values, skin rashes, reddening of the skin, itching and urticaria (hives) may occur. Dizziness and headaches may occur.

Rarely (affects 1 to 10 in 10,000 people treated):

Inflammation of the tongue or oral mucosa. Rarely, superficial tooth discoloration was observed. This usually disappears after brushing the teeth. Inflammation of the liver (hepatitis) and jaundice have rarely been reported.

Very rare (affects less than 1 in 10,000 people treated):

Hyperactivity, agitation, anxiety, insomnia, confusion, behavioral changes, drowsiness, convulsions, sensory disturbances and severe persistent diarrhea may occur. A dark coated tongue, hyperkinesia (excessive locomotor activity), Blood count changes, prolongation of bleeding time and prothrombin time, kidney inflammation and kidney dysfunction observed. Very rarely, flu-like symptoms Symptoms with rash, fever, swollen glands and abnormal blood counts (including white blood cells (eosinophilia) and liver enzymes) (drug rash with eosinophilia and systemic symptoms (DRESS)) have been observed (see "When to take Augmentin with caution"). Cases of serious skin reactions have been reported.

When administering amoxicillin at the age of 0-9 months, enamel damage (e.g. white streaking, discoloration) of the permanent incisors cannot be ruled out.

Very rarely, a red rash, often occurring on both sides of the buttocks, upper inner thighs, armpits and neck (Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE)) has been reported.

Frequency unknown (cannot be estimated from the available data):

Inflammation of the meninges (aseptic meningitis), crystals in the urine that could lead to acute kidney damage. Severe and persistent pain in the stomach area, which could be a sign of acute pancreatitis (inflammation of the pancreas).

Skin rashes with circularly arranged blisters with central crust formation or arranged like a string of pearls (linear IgA disease) have been reported. Drug-induced enterocolitis syndrome (DIES): DIES has been reported mainly in children who have received amoxicillin (with or without clavulanic acid). It is a specific type of allergic reaction with the main symptom being persistent vomiting (1-4 hours after taking the drug). Other symptoms may include abdominal pain, lethargy, diarrhea and low blood pressure. If such allergic reactions occur, Augmentin should be discontinued immediately. You should contact a doctor to consider an alternative therapy.

Chest pain has been observed very rarely, which may be a sign of a potentially serious allergic reaction, the known as Kounis syndrome.

If Augmentin is taken at the beginning of meals, gastrointestinal complaints are less common.

Consult your doctor immediately if you experience:

- nettle fever, extensive rash, reddening of the skin;
- yellowish color of the skin or white part of the eyes;
- sudden onset of abdominal pain or vomiting;
- severe, bloody or persistent diarrhea;
- Breathing problems in the form of asthma attacks and hay fever.

If you get any side effects, inform your doctor or pharmacist immediately. This applies in particular to side effects that are not specified in this patient information leaflet.

To report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s, please contact us via: gulf.safety@gsk.com.

What should also be noted?

The medicinal product should only be used until the date marked "EXP" on the package.

Storage instructions

Store in a dry place at or below 30°C.

Keep out of reach of children.

Store in the original package in order to protect from moisture.

Tablets in desiccated pouch packs should be used within 14 days of opening.

More information

If you notice discoloration of the Augmentin film-coated tablets, it could be a change in the preparation. If this happens, contact your doctor or pharmacist immediately.

After the end of treatment, the medicinal product and the remaining contents of your delivery point (doctor or pharmacist) should be disposed of properly. Your doctor or pharmacist will give you further information. These people have the detailed information.

What does Augmentin contain?

Active ingredients

Augmentin contains the active substances amoxicillin (as amoxicillin trihydrate) and clavulanic acid (as potassium salt). Below is the detailed composition of the various commercially available film-coated tablets:

1 film-coated tablet contains:	Amoxicillin	Clavulanic acid	Amoxicillin / clavulanic acid ratio
Augmentin 1 gm (875/125) film-coated tablets	875 mg	125 mg	7 : 1

List of Excipients

Colloidal silicon dioxide, sodium starch glycolate, magnesium stearate (E572), microcrystalline cellulose, titanium dioxide (E171), hydroxypropyl methylcellulose, polyethylene glycol, dimethicone (silicon oil).

Augmentin is supplied in a carton containing 14 tablets in blisters inside a desiccated pouch.

Manufactured by:

SmithKline Beecham Limited*

Worthing, United Kingdom

*Member of the GlaxoSmithKline group of companies

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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 emergence of resistant bacteria that could stop the antibiotic working.

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. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. 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.
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 that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

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FRONT

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