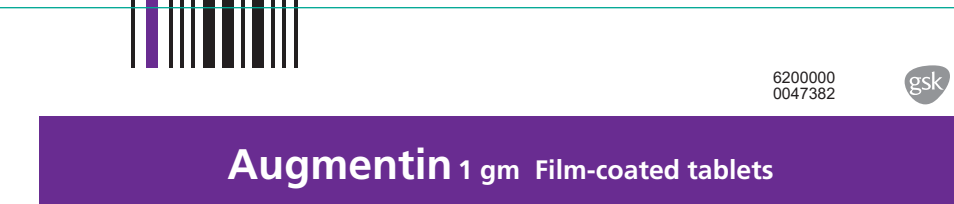


Pharma code Ref. No. 5223



6200000
0047382



Augmentin 1 gm Film-coated tablets



Package leaflet Information for the patient

Read all of this leaflet carefully before you start taking this medicine. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

Keep this leaflet. You may need to read it again.

Augmentin 1 gm Film-coated tablets

What Augmentin is and what it is used for

Augmentin is an antibiotic in the group of penicillins. It contains two medicines called clavulanic acid and amoxicillin.

Clavulanic acid can overcome the main mechanism of resistance of many bacteria that are resistant to penicillins and in this way protects amoxicillin so that it can destroy the bacteria. This action means that Augmentin is effective against many bacterial infections.

Augmentin should only be used when prescribed by a doctor for the exclusive treatment of the following bacterial infections:

- Nose, throat, tonsil, front/maxillary sinus and ear infections;
- Respiratory infections (bronchi and lungs);
- Infections of the kidneys, bladder and urinary tract;
- Infections of the genital organs (gonorrhoea, secretion of mucus);
- Gynaecological infections;
- Infections of the skin and soft tissues (boils, abscesses, etc.).

Warnings and precautions

This medicine has been prescribed for you by your doctor to treat your current disease.

The antibiotic in Augmentin is not effective against all micro-organisms that cause infectious diseases. Using the wrong antibiotic or the wrong dose of the antibiotic can cause complications. Therefore, never use it for the treatment of other diseases or other people. You must also not use it for subsequent new infections without consulting a doctor.

The signs of illness often disappear before the infection has been completely cured. This means that the treatment must not be interrupted early, even if you feel better.

Depending on the circumstances and as instructed by the doctor, the treatment may last up to two weeks or longer.

When not to take Augmentin

You should not take Augmentin if you had an allergic reaction previously to Augmentin, penicillin or cephalosporin. An allergy or hypersensitivity manifests as symptoms such as red spots on the skin, fever, asthma, respiratory distress, circulatory problems, swelling of the skin (e.g. hives) and mucous membranes, skin rashes or a painful tongue.

In cases of known or suspected hypersensitivity to any of the other ingredients of the medicine, Augmentin must not be used.

You must not take Augmentin if you have mononucleosis or lymphocytic leukaemia.

Special precautions to be taken when using Augmentin

This medicine may affect responsiveness and the ability to drive and use tools or machines.

If you are taking an oral contraceptive (the pill), its efficacy may be reduced during an antibiotic therapy. This also applies to Augmentin. Therefore, your doctor or pharmacist can recommend additional contraceptive measures.

Indigestion may occur during the use of Augmentin. In severe gastrointestinal disturbances, with vomiting and diarrhoea, the medicine should be stopped and the doctor should be seen immediately. A doctor should also be contacted if a skin rash or itching appears.

If diarrhoea occurs, no medicine that inhibits intestinal peristalsis (intestinal motility) must be taken.

If you have allergies, allergic asthma, hay fever or hives, special caution is advised when using Augmentin due to possible hypersensitivity reactions.

Patients who need to take allopurinol-containing medicines at the same time (e.g. Zyloric) are more prone to rashes.

Check with your doctor if you have a kidney function disorder; he/she will prescribe a dosage tailored to fit your needs and it may differ from those shown in the "Usual dosage" section below.

Check with your doctor if you are using blood thinners (anticoagulants).

Check with your doctor if you are using mycophenolate mofetil-containing medicines given following organ transplants as prophylaxis for acute graft rejection reactions.

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

Extreme caution is required in cases of decreased kidney or liver function.

Check with your doctor or pharmacist if you

- have other diseases,
- have allergies or
- are taking or applying other medicines (including over-the-counter drugs) externally.

Pregnancy and breast-feeding

Pregnancy

The use of medicines of any kind should be decided during pregnancy with the greatest caution and only after consulting your doctor or pharmacist. In studies in pregnant women with premature rupture of the membranes, preventive treatment with Augmentin has been reported to be associated with an increased risk of sometimes serious tissue-damaging inflammatory bowel disease in the newborn.

Breast-feeding

Because Augmentin is excreted in small amounts in breast milk, there is the possibility of a hypersensitivity reaction (with symptoms such as rash and fever) or diarrhoea in the infant. Therefore, Augmentin should not be taken during breast-feeding or should be stopped.

In any case, see your doctor or pharmacist if you are or could be pregnant or are breast-feeding. They are the only ones who can decide whether you can take Augmentin during those periods.

How to use Augmentin

Usual dosage

Augmentin is best taken at the start of a meal, with at least half a glass of water. This will ensure optimal action and tolerability. Unless prescribed otherwise by the doctor, the dosage is as follows:

Adults

Mild, moderate and severe infections:

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

Once started, antibiotic therapy should be continued as long as prescribed by the doctor.

The signs of illness often disappear before the infection has been completely cured. Therefore, do not stop the therapy early, even if you feel better.

Do not change from the prescribed dose. If you believe that the medicine is too weak or too strong, talk to your doctor or pharmacist.

Possible side effects of Augmentin

Gastrointestinal disorders such as stomach discomfort or queasiness. Reactions such as nausea, loss of appetite, bloating, vomiting, diarrhoea, loose stools, dyspepsia, abdominal pain and inflammation of the tongue or oral mucosa may also occur.

Gastrointestinal symptoms are less common when Augmentin is taken at the start of a meal.

Allergic reactions are common with Augmentin, as with all medicines in the group of penicillins.

Rashes, redness, itching and urticaria (hives) may occur.

Fungal infections of the skin/mucous membranes may also occur.

Dizziness and headaches can sometimes occur.

In rare cases, hyperactivity, agitation, anxiety, insomnia, confusion, behavioural changes, light-headedness, seizures and sensory disturbances can occur.

Superficial tooth discolouration has been observed in rare cases. This usually disappeared with brushing.

Very rarely, a dark coated tongue, hyperkinesia (excessive locomotor activity), blood count changes,

prolongation of bleeding time and prothrombin time, liver inflammation (hepatitis), inflammation of the kidneys and kidney function disorders have been observed.

When administering amoxicillin between the ages of 0 and 9 months, enamel damage (such as white streaks, discolouration) of the permanent incisors cannot be excluded.

Jaundice has been reported rarely.

See your doctor immediately if the following occur:

- Hives, skin rash over large areas of the skin reddening of the skin;
- Yellowish colour of the skin or white part of the eyes;
- Sudden onset of stomach pain or vomiting;
- Severe, bloody or persistent diarrhoea;
- Breathing problems in the form of asthma attacks and hay fever.

If you notice side effects not described here, you must inform your doctor or pharmacist.

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.

Other precautions

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

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

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

If you notice any discolouration of the Augmentin film-coated tablets, there may have been a change in the medicine. If this happens, see your doctor or pharmacist immediately.

Do not use this medicine after the expiry date which is stated on the pack after "EXP".

See your doctor or pharmacist for further information. These people have the detailed information for specialists.

What Augmentin contains

Augmentin contains the medicines amoxicillin (as amoxicillin trihydrate) and clavulanic acid (as a potassium salt). The detailed composition of the different film-coated tablets sold is as follows:

1 film-coated tablet contains:	Amoxicillin	Clavulanic acid	Ratio of Amoxicillin to Clavulanic acid	Ingredients
Augmentin 1 g (875/125) film-coated tablets	875 mg	125 mg	7 : 1	Ingredients for preparation of the film-coated tablets

List of Excipients

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

Where to get Augmentin. Contents of the pack.

Available in pharmacies against a doctor's prescription that may only be filled once.

Augmentin 1 g (875/125) film-coated tablets: 14 film-coated tablets.

Manufactured by:

SmithKline Beecham Limited*

Worthing, United Kingdom

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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 medication

- The doctor and the pharmacist are the experts in medicines, their benefits and risks

- Do not by yourself interrupt the period of treatment prescribed

- Do not repeat the same prescription without consulting your doctor

- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists.

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		527	
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Total Special Finishes: 0			
Body Text Size: 7.0pt			
Smallest Text Size: 7.0pt			
Leading: 8.0pt			
Horizontal Scale: 100%			
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200 mm Measuring Bar

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NOTE TO MARKET

Local approvers must ensure that trade mark and copyright statements included in the brief comply with guidance provided by Legal: Global Trade Marks.

IMPORTANT

GSK LOC is responsible to approve the change documentation, artwork brief and final artwork, ensuring that it is accurate, consistent and complete.

GSK SDC is responsible for site technical requirements and pre-press suitability.

GSK Market is responsible to advise SDC when changes required impact the following:

Formulation
Tablet embossing
Storage conditions
Shelf Life

