
	Project: CO-0028176	Document: PPC-0023427	Version: 3
	Site Code: 62000000049895	Operator: HAB14777	Date/Time Created: 29.Jun.2020 23:43 GMT+1

Version: 1		
Harmony AMS Artwork Information Panel		
Manufacturing Site Number: 62000000049895		
Manufacturing Site(s): GSK_WORTHING_UNITED KINGDOM		
Product Market Trade Name: Augmentin		
Approving Market(s): MARKET GROUP-Gulf and Near East		
Print Process: N/A		
Colour Standard Reference: N/A		
Technical Drawing (Do NOT include version number): LF035		
Material Spec. (Do NOT include version number): N/A		
Material Type: N/A		N/A
Total Colours & Varnishes: 1		
		BLACK
Total Special Finishes: 0		
Body Text Size: 6.0pt		
Smallest Text Size: 6.0pt		
Leading: 6.5pt		
Horizontal Scale: 100%		
Microtext: N		
Additional Info (1): N/A		
Additional Info (2): N/A		
Additional Info (3): N/A		

200 mm Measuring Bar
If an e-banner DOES NOT appear on the top of this document, THEN this document has NOT been printed from the Harmony system.

AIP_Production_V_INDD - 04_2017 - Harmony - Version 2

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.

PHARMA CODE N° 5201



Package leaflet: Information for the user

6200000
0049895



Augmentin 375 mg Tablets

Amoxicillin trihydrate and Potassium clavulanate



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you (or for your child) only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Augmentin is and what it is used for
- What you need to know before you take Augmentin
- How to take Augmentin
- Possible side effects
- How to store Augmentin
- Contents of the pack and other information

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:

- sinus infections
- urinary tract infections
- skin infections
- dental infections.

2 What you need to know before you take Augmentin

Do not take Augmentin:

- if you are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6)
- if you have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

→ **Do not take Augmentin if any of the above apply to you.** If you are not sure, talk to your doctor or pharmacist before taking Augmentin.

Warnings and precautions

- Talk to your doctor or pharmacist before taking Augmentin if you:
- have glandular fever
 - are being treated for liver or kidney problems
 - are not passing water regularly.
- If you are not sure if any of the above apply 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.

Conditions you need to look out for

Augmentin 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 Augmentin, to reduce the risk of any problems. See "Conditions you need to look out for" in section 4.

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 types of tests.

Other medicines and Augmentin

- Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.
- If you are taking allopurinol (used for gout) with Augmentin, it may be more likely that you will have an allergic skin reaction.
 - If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Augmentin.
 - If medicines to help stop blood clots (such as warfarin) are taken with Augmentin then extra blood tests may be needed.
 - Augmentin can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
 - Augmentin may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy, breast-feeding and fertility

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.

Driving and using machines

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.

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.

Adults and children weighing 40 kg and over

The usual dose is:

- 1 tablet three times a day

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with Augmentin oral suspension or sachets. Augmentin tablets are not recommended.

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed. A different strength or different medicine may be chosen by your doctor.
- If you have liver problems you may have more frequent blood tests to check how your liver is working.

How to take Augmentin

- Take with a meal.
- Swallow the tablets whole with a glass of water.
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Augmentin for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Augmentin than you should

If you take too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible. Take the medicine carton or bottle to show the doctor.

If you forget to take Augmentin

- if you forget to take a dose take it as soon as you remember.
- You should not take the next dose too soon, but wait around 4 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Augmentin

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. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

Conditions you need to look out for

Allergic reactions:

- skin rash
- 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 throat (*angioedema*), causing difficulty in breathing
- collapse.

→ **Contact a doctor immediately** if you get any of these symptoms. **Stop taking Augmentin.**

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

- thrush (*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.

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*)

→ if you notice any of these symptoms contact a doctor urgently.

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

- low number of cells involved in blood clotting
- low number of white blood cells.

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 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 small pus-containing blisters (*bullous exfoliative dermatitis*)
- a red, scaly rash with bumps under the skin and blisters (*exanthematous 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)*).

→ **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*)

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. By reporting side effects you can help provide more information on the safety of this medicine. 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.

5 How to store Augmentin

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.
- 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.
- Do not use if the tablets are chipped or damaged.
- 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.

6 Contents of the pack and other information

What Augmentin contains

- The active substances are amoxicillin and clavulanic acid. Each tablet contains amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 125 mg of clavulanic acid.
- Other ingredients are: Tablet core – magnesium stearate, sodium starch glycolate type A, colloidal anhydrous silica, microcrystalline cellulose. Film coat – titanium dioxide (E171), hypromellose, macrogol (4000, 6000) and silicone oil (dimeticone).

What Augmentin looks like and contents of the pack

Augmentin 375 mg film-coated tablets are white to off-white, oval shaped tablets debossed with "Augmentin" on one side. They are packaged in blister packs inside a pouch, enclosed in a carton. The pouch contains a desiccant sachet. The desiccant must be kept inside the pouch and must not be eaten.

Manufacturer:

SmithKline Beecham Limited*

Worthing, United Kingdom

*Member of the GlaxoSmithKline group of companies

This leaflet was last revised in January 2019.

Trade marks are owned by or licensed to the GSK group of companies.

© 2020 GSK group of companies or its licensor.

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.

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

