AUGMENTIN BD

Patient Information Leaflet

Scheduling status:

S4

Proprietary name, strength and pharmaceutical form:

AUGMENTIN BD Tablets

Amoxicillin 875 mg and clavulanic acid 125 mg

Sugar Free

Read all of this leaflet carefully before you start taking AUGMENTIN BD:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist, nurse or other healthcare provider.
- AUGMENTIN BD has been prescribed for you personally, and should not be shared with other people. It may harm them, even if their symptoms are the same.

What is in this leaflet

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

1. What AUGMENTIN BD is and what it is used for:

AUGMENTIN BD is an antibiotic which works by killing bacteria that cause infections. It contains two active ingredients; a penicillin called amoxicillin and clavulanic acid.

AUGMENTIN BD tablets are used to treat certain bacterial infections.

2. What you need to know before you take AUGMENTIN BD:

Do not use AUGMENTIN BD if:

- you are allergic to amoxicillin, penicillins or cephalosporins, or to any of the other ingredients of AUGMENTIN BD. If you have had an allergic reaction (such as a rash) when taking an antibiotic, you should talk to your doctor before taking AUGMENTIN BD
- you had jaundice (yellowing of the skin and/or eyes) or liver disease while taking AUGMENTIN BD.

Warnings and precautions:

Take special care with AUGMENTIN BD if:

- you develop a skin rash while taking AUGMENTIN BD. Do not take more AUGMENTIN BD and tell the doctor at once
- you have glandular fever and are prescribed AUGMENTIN BD. Please tell the doctor before you take the medicine
- you have liver or kidney problems. The dosage may need to be reduced or you may need to be given a different medicine
- you are not passing urine regularly and not able to drink water.

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 BD or a different medicine.

Conditions you need to look out for:

AUGMENTIN BD can make some existing conditions worse or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine (pseudomembranous colitis). You must look out for certain symptoms while you are taking AUGMENTIN BD, to reduce the risk of any problems. See POSSIBLE SIDE EFFECTS.

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 BD. This is because AUGMENTIN BD can affect the results of these type of tests.

Other medicines with AUGMENTIN BD:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

It is particularly important that the doctor knows if you are taking the following medicines:

- allopurinol
- probenecid
- anti-coagulants (used to prevent blood clots) such as warfarin.
- mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs).

AUGMENTIN BD with food, drink and alcohol:

It is better to take AUGMENTIN BD at the same time as a meal, but AUGMENTIN BD still works if it is taken without food. Remember to drink plenty of fluids such as water or non-alcoholic drinks.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

If you are taking a contraceptive pill, you should talk to your doctor before taking AUGMENTIN BD.

Driving and using machines:

It is not always possible to predict to what extent AUGMENTIN BD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which AUGMENTIN BD affects them.

3. How to take AUGMENTIN BD:

Do not share medicines prescribed for you with any other person.

You must follow your doctor's advice and use AUGMENTIN BD as instructed. Your doctor will decide how much AUGMENTIN BD you need to take each day, and how many days you should take it for.

If there is anything you do not understand please ask your doctor or pharmacist.

It is better to take AUGMENTIN BD at the same time as a meal, but AUGMENTIN BD still works if it is taken without food. Remember to drink plenty of fluids such as water or non-alcoholic drinks.

Once you have started taking AUGMENTIN BD:

Keep taking AUGMENTIN BD until the complete course has been finished. Do not stop treatment early, even if you feel better.

If you take more AUGMENTIN BD than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Drink plenty of water and contact a doctor. Show the doctor the pack of AUGMENTIN BD.

If you forget to take AUGMENTIN BD:

Take it as soon as you remember, then continue as before. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects:

AUGMENTIN BD can have side effects.

Not all side effects reported for AUGMENTIN BD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AUGMENTIN BD please consult your healthcare provider for advice.

If you have any of the following symptoms after taking AUGMENTIN BD, STOP taking it and tell your doctor immediately, or go to the accident and emergency department of your nearest hospital:

- sudden wheeziness, shortness of breath, or chest tightness
- swelling of the face, lips, tongue, or other parts of the body
- suddenly feeling faint, especially upon standing up
- convulsions (fits or seizures)
- yellowing of the skin and/or eyes, or dark coloured urine. These symptoms may be accompanied by itching, fever, nausea, vomiting, loss of appetite and feeling generally unwell. These symptoms may not occur until several weeks after the end of treatment and can be severe
- blood in the urine which may be associated with a rash, fever, joint pain, or a reduction in passing water (urination)
- severe diarrhoea, which may be bloody, or contain mucus, and which may be accompanied by stomach cramps
- a rash with blisters that may cause the skin to peel, flake, or bleed

- unusual tiredness, headaches, being short of breath when exercising, dizziness, looking pale.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AUGMENTIN BD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fever, severe chills, sore throat or mouth ulcers. Unusual joint pains especially if accompanied by a rash
- the tongue may change colour to yellow, brown or black, and it may have a hairy appearance
- bleeding, or bruising, more easily than usual
- a rash where the spots (usually 0,5 cm to 2 cm in size) have a pink/red ring around the edge and a darker centre.
- inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- 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)).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- mild rash, itching or hives (itchy lumps)
- indigestion
- headache
- dizziness
- diarrhoea (loose, or watery bowel movements.)
- nausea (feeling sick)

- vomiting (being sick)
- thrush (a yeast infection of the vagina, mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist.
- Symptoms such as indigestion, feeling sick and being sick can often be avoided by giving AUGMENTIN BD at the beginning of a meal.
- Teeth can become discoloured while using AUGMENTIN BD. This is less likely to happen if you clean your teeth thoroughly, and any discolouration can usually be removed by brushing. If the discolouration does not disappear, ask your doctor or dentist for advice.

Not all side effects reported for AUGMENTIN BD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AUGMENTIN BD.

5. How to store AUGMENTIN BD:

Store all medicines out of reach of children.

The expiry date of this medicine is printed on the label. Do not use the medicine after this date.

The medicine should be stored in a dry place, at or below 30 °C.

Keep in the original packaging to protect from light.

Do not remove the desiccant pouch.

Use within 14 days of opening

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information:

What AUGMENTIN BD contains:

Each tablet contains the active substances 875 mg amoxicillin and 125 mg clavulanic acid. The other ingredients are colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, titanium dioxide (E171), hydroxypropyl methylcellulose, polyethylene glycol and silicone oil.

What AUGMENTIN BD looks like and contents of the pack:

White to off-white, capsule shaped, film-coated tablets, debossed with AC' on both sides with a score-line on one side. The 10's pack consists of one aluminium pouch, containing a desiccant and a blister strip of 10 tablets. The blister is composed of a PVC/PVdC laminate and grey aluminium foil.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

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This leaflet was last revised in:

13 January 2021

Registration number:

32/20.1.2/0239

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