PATIENT LEAFLET

AUGMENTIN BD S

AUGMENTIN BD SF

Amoxicillin trihydrate and Potassium clavulanate

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have any questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.

In this leaflet

What AUGMENTIN BD S or AUGMENTIN BD SF is and what it is used for

AUGMENTIN BD S or AUGMENTN BD SF is an antibiotic used in adults and children to treat infections in different parts of the body caused by certain types of bacteria.

AUGMENTIN BD S or AUGMENTN BD SF contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin is a penicillin antibiotic. Amoxicillin can

sometimes be stopped from working (made inactive). The other active medicine, clavulanic acid, stops this from happening.

Before you take AUGMENTIN BD S or AUGMENTIN BD SF

Don't take AUGMENTIN BD S or AUGMENTIN BD SF

- if you're **allergic** (*hypersensitive*) to amoxicillin, clavulanic acid, other penicillin-based antibiotics, or similar antibiotics called cephalosporins.
- if you have ever had **liver problems** or **jaundice** (*yellowing of the skin and/or whites of the eyes*) when taking an antibiotic.

➔ if you think any of these apply to you, **check with your doctor** before you take AUGMENTIN.

Take special care with AUGMENTIN BD S or AUGMENTIN BD SF

Before you take AUGMENTIN your doctor needs to know:

- if you have ever had an **allergic reaction** to any other antibiotics or medicines. This might include a skin rash or swelling of the face or neck.
- if you have **glandular fever** (**mononucleosis**)
- if you're taking medicines, such as warfarin, that are used to **prevent blood clots**
- If you have **liver problems**
- if you have **kidney disease**
- if you're not **urinating regularly** or not able to **drink** very much.
- if you have a genetic condition called phenylketonuria (***see also "AUGMENTIN BD S and AUGMENTIN BD SF contain aspartame"*** *later in Section 2)*

➔ **Check with your doctor** if you think any of these may apply to you. Your doctor will decide whether AUGMENTIN is suitable for you and may need to adjust your dose or give you a different medicine.

Look out for important symptoms

AUGMENTIN can make some existing conditions worse, or cause serious side effects, such as **severe allergic reactions, serious skin reactions, chest pain, repetitive vomiting within 1 to 4 hours of AUGMENTIN administration, serious liver problems or severe diarrhoea** or **inflammation of the large intestines (pseudomembranous colitis)**. You must look out for certain symptoms while you're taking AUGMENTIN to help reduce the risk of any problems. See '*Look out for important symptoms*' in **Section 4**.

Other medicines and AUGMENTIN BD S or AUGMENTIN BD SF

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.

Some medicines may affect how AUGMENTIN works, or make it more likely that you'll have side effects. AUGMENTIN can also affect how some other medicines work. These include:

- **probenecid** and **allopurinol** (used to **treat gout**).
- **anticoagulants** (used to **prevent blood clots**) such as warfarin and acenocoumarol.
- **mycophenolate mofetil** (a medicine used to **prevent the rejection of transplanted organs**).
- methotrexate (used to treat conditions such as cancer and severe psoriasis).

➔ Tell your doctor or pharmacist if you're taking any of these.

AUGMENTIN may reduce how well the **contraceptive pill** works. If you're taking the contraceptive pill while you're being treated with AUGMENTIN, you should also use a **barrier method of contraception** (such as condoms). Ask your doctor for advice.

Pregnancy and breast-feeding

If you're **pregnant**, or **think you could be**, or if you're **planning to become pregnant**,

don’t take AUGMENTIN without checking with your doctor. **Your doctor** will consider the benefit to you and the risk to your baby, of taking AUGMENTIN while you’re pregnant.

You can usually breast-feed while you’re taking AUGMENTIN; if you’re breast-feeding or considering breast-feeding, **check with your doctor before you take** AUGMENTIN.

AUGMENTIN BD S and AUGMENTIN BD SF contain aspartame

AUGMENTIN BD S and AUGMENTIN BD SF contain **aspartame**, which is a source of phenylalanine. If you have an intolerance to aspartame or have a condition called **phenylketonuria (PKU)**:

➔ **Check with your doctor** that AUGMENTIN is right for you.

How to take AUGMENTIN BD S OR AUGMENTIN BD SF

Always take AUGMENTIN exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you're not sure.

How much to take

Your doctor will decide on the correct dosage for you

Patients with kidney or liver problems

- If you have kidney problems, your doctor may give you a different strength or a different medicine.
- If you have liver problems, you may have more frequent blood tests to check how your liver is working.

How to take

- Take AUGMENTIN at the start of a meal or slightly before.
- Instructions on how to prepare your AUGMENTIN suspension are provided at the end of this leaflet.

- Shake the bottle well before taking each dose.
- A dosing syringe, spoon or cup may be supplied with the pack, which you can use to measure the dose accurately.
- A dosing syringe should be used to give the correct dose to children below 3 months. Instructions on how to use the dosing syringe are provided at the end of this leaflet.

Do not take AUGMENTIN for more than 14 days. If you still feel unwell you should go back to **see your doctor.**

If you forget to take AUGMENTIN BD S or AUGMENTIN BD SF

Don't take a double dose to make up for a missed dose. Just take it as soon as you remember.

If you're not sure what to do, ask your doctor or pharmacist.

If you take too much AUGMENTIN BD S or AUGMENTIN BD SF

If you accidently take too much AUGMENTIN, it is unlikely to cause any serious problems. The most common side effects of taking too much AUGMENTIN are nausea, vomiting and diarrhoea. If you're worried, or you feel unwell:

➔ Ask your doctor or pharmacist for advice.

Don't stop taking AUGMENTIN BD S or AUGMENTIN BD SF without advice

It is important that you take the full course of AUGMENTIN. Don't stop unless your doctor advises you to – even if you're feeling better. If you don't complete the full course of treatment, the infection may come back.

Possible side effects

Like all medicines, AUGMENTIN can cause side effects, but not everybody gets them.

Look out for important symptoms

Severe allergic reactions

These are very rare in people taking AUGMENTIN. Signs include:

- raised, itchy rash (*hives*)
- 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 mouth (*angioedema*), which may cause difficulty in swallowing or breathing
- collapse.
- chest pain which can be a sign of a potentially serious allergic reaction called *Kounis syndrome*.
- repetitive vomiting (1 to 4 hours after AUGMENTIN administration), stomach pain, abnormal drowsiness, diarrhoea and low blood pressure which can be a sign of a serious allergic reaction called *drug-induced enterocolitis syndrome*.

➔ **Get medical help immediately** if you get any of these symptoms. **Stop taking AUGMENTIN.**

Serious skin reactions

These are rare in people taking AUGMENTIN. Signs include:

- 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*).

These are very rare in people taking AUGMENTIN. Signs include:

- 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 blisters and peeling skin on much of the body surface (*toxic epidermal necrolysis*)
- a widespread, red, skin rash with small blisters containing pus (*exanthemous pustulosis*)
- a red, itchy, scaly rash with blisters and bumps under the skin (*bullous exfoliative dermatitis*)

- 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))*.
- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck (*Symmetrical Drug-related Intertriginous and Flexural Exanthema (SDRIFE)*).

➔ **Get medical help immediately** if you get any of these symptoms**. Stop taking AUGMENTIN.**

Serious liver problems

On rare occasions, medicines like AUGMENTIN can cause liver problems, causing yellowing of the skin and/or whites of the eyes.

➔ Tell your doctor as soon as possible if you get any of these symptoms.

Severe diarrhoea (*Pseudomembranous colitis*)

On rare occasions, medicines like AUGMENTIN can cause inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain and fever.

➔ Tell your doctor as soon as possible if you get any of 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 (fungal infection caused by *Candida* in the vagina, mouth or skin folds)
- feeling sick (*nausea*)
- vomiting
- diarrhoea (in children).

Uncommon side effects

These may affect **up to 1 in 100** people:

- dizziness
- headache
- indigestion
- skin rash
- itching
- itchy, bumpy rash (*hives*)

Uncommon side effects that may show up in blood tests are:

- increase in some substances (enzymes) produced by the liver

Rare side effects

These may affect **up to 1 in 1,000** 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 multiform*e) (See *'serious skin reactions'* earlier in Section 4)

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

- decrease in the number of white blood cells (*leucopenia*, including *neutropenia)*
- decrease in the number of cells that help blood to clot (*thrombocytopenia*)

Very rare side effects

These may affect **up to 1 in 10,000** people:

- severe allergic reactions (*See also **'severe allergic reactions'** earlier in Section 4*)
- serious skin reactions (*See also **'serious skin reactions'** earlier in Section 4*)
- inflammation of the liver (*hepatitis*) (*See also **'serious liver problems'** earlier in Section 4*)
- yellowing of the whites of the eyes or skin (*jaundice*) (*See also **'serious liver***

problems' *earlier in Section 4*)

- inflammation of the large intestines (*See also* ***'severe diarrhoea'*** *earlier in Section 4*)
- inflammation of the kidney (*nephritis*)
- an increase in the time blood takes to clot
- being unusually active (*hyperactivity*)
- fits (*seizures*)
- black tongue which looks hairy
- stained teeth that can usually be removed by brushing
- inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- rash with blisters arranged in a circle with central crusting or like a string of pearls (*linear IgA disease*).

Very rare side effects that may show up in blood or urine tests are:

- severe decrease in the number of white blood cells (*agranulocytosis*)
- red blood cells destroyed too quickly (*haemolytic anaemia*)
- crystals in urine

➔ **Tell your doctor or pharmacist** if any of the side effects listed becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

How to Store AUGMENTIN BD S or AUGMENTIN BD SF

Keep out of the sight and reach of children.

Do not take AUGMENTIN after the expiry date shown on the pack.

Store in a dry place at or below 30 °C in the original packaging to protect from moisture.

Once made up, the suspension should be stored in a refrigerator (2 °C to 8 °C).

Do not freeze.

Dispose of any unused suspension 7 days after first making up.

Don’t dispose of medicines in waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Further information

What AUGMENTIN BD S or AUGMENTIN BD SF contains

The active substances are amoxicillin and clavulanic acid.

Bottles of AUGMENTIN BD S or AUGMENTIN BD SF powder for oral suspension comes in different strengths.

Each 5 ml of reconstituted suspension contains either:

- amoxicillin trihydrate equivalent to 200 mg amoxicillin and potassium clavulanate equivalent to 28.5 mg clavulanic acid
- amoxicillin trihydrate equivalent to 400 mg amoxicillin and potassium clavulanate equivalent to 57 mg clavulanic acid

The other ingredients are: xanthan gum, hydroxypropylmethylcellulose, colloidal silica, succinic acid, silicon dioxide, aspartame and dry flavours (raspberry, orange “1”, orange “2” and golden syrup).

Sugar-free. Contains sweetener (aspartame 12.5 mg/5 mL).

What AUGMENTIN BD S or AUGMENTIN BD SF looks like and contents of the pack

Clear glass bottles containing powder for reconstitution. Bottles may be supplied with either an aluminium screw cap with a ring seal or a plastic child-resistant cap with a removable foil-backed seal on the bottle. Fill-lines are indicated on the bottle label. Bottles may be supplied with a plastic dosing device.

Name and address of the holder of the certificate of registration

GlaxoSmithKline South Africa (Pty) Ltd

57 Sloane Street

Bryanston, 2021

South Africa

Registration details

Botswana:
AUGMENTIN BD SF – Reg No BOT1502714 S2
Malawi:
AUGMENTIN BD SF – Reg No PMPB/PL270/183 POM
Namibia:
AUGMENTIN BD S – Reg No 04/20.1.2/1735 NS2
AUGMENTIN BD SF – Reg No 04/20.1.2/1736 NS2
Zambia:
AUGMENTIN BD S – Reg No 179/009 POM
AUGMENTIN BD SF – Reg No 179/046 POM

Information for healthcare professionals

For bottles with aluminium screw caps, check the cap ring seal is intact before using. Alternatively, for bottles with a plastic child-resistant cap, check the foil-backed bottle seal is intact before using.

At time of use, the dry powder should be reconstituted to form an oral suspension, as detailed below:

- Check cap seal is intact before use.
- Invert and shake bottle to loosen powder.
- Add volume of water (indicated below). Invert and shake well
- Alternatively, fill the bottle with water to just below the mark on bottle label. Invert and shake well, then top up with water to the mark. Invert and shake again.
- Allow to stand for 5 minutes to ensure full dispersion.
- Shake well before taking each dose.

AUGMENTIN BD S

Fill Weight (g)	Volume of water to be added to reconstitute (mL)	Final volume of reconstituted oral suspension (mL)
7.7	64	70
15.4	128	140

AUGMENTIN BD SF

Fill Weight (g)	Volume of water to be added to reconstitute (mL)	Final volume of reconstituted oral suspension (mL)
6.3	31	35
12.6	62	70
25.2	124	140

A plastic dosing device may be supplied with the pack which can be used to measure the dose accurately.

Discard any unused suspension after 7 days.

Not all presentations are available in every country.

Version number: ***GDS29/IPI18***

Date of issue: ***17 January 2024***