

AUGMENTIN(R) DUO & AUGMENTIN(R) DUO FORTE TABLETS

Amoxicillin & Clavulanic Acid

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets.

This leaflet answers some common questions about AUGMENTIN DUO and AUGMENTIN DUO FORTE tablets.. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of you taking AUGMENTIN tablets against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What are AUGMENTIN DUO and AUGMENTIN DUO FORTE tablets used for?

AUGMENTIN tablets contain two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid.

AUGMENTIN tablets belong to the penicillin group of antibiotics.

AUGMENTIN tablets are used to treat a wide range of infections caused by bacteria. These infections may affect the chest (bronchitis or pneumonia), bladder (cystitis), sinuses (sinusitis), the ears (otitis media) or the skin.

AUGMENTIN tablets work by killing the bacteria that cause these infections. AUGMENTIN tablets will not work against infections caused by viruses such as colds or the flu.

Your doctor may prescribe AUGMENTIN tablets for another use. If you want more information ask your doctor.

There is no evidence that AUGMENTIN tablets are addictive.

Before you take AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets

Do not take AUGMENTIN tablets if:

- * you have had an allergic reaction to penicillin or similar types of antibiotics (such as cephalosporins) or any of the ingredients contained in AUGMENTIN DUO or

AUGMENTIN DUO FORTE tablets.

The ingredients are listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty in breathing and swelling of the face or tongue.

- * you have previously experienced liver problems after taking AUGMENTIN tablets or any other medicines.
- * the expiry date (EXP) printed on the pack has passed.
- * the packaging is torn or shows signs of tampering.
- * Do not give this medicine to anyone else; your doctor has prescribed it specifically for you and your condition.
- * If you are not sure whether you should start taking AUGMENTIN tablets, talk to your doctor.

Tell your doctor if:

- * you have ever had an allergic reaction (such as a rash) to antibiotics or other substances in the past.
- * you are allergic to foods, dyes, preservatives or any other medicines.
- * you have experienced liver problems after taking AUGMENTIN tablets or any other medicines.

- * you have glandular fever (mononucleosis) or leukaemia.
- * you are pregnant or think you may be pregnant or are breast-feeding.

Your doctor will discuss with you the possible risks and benefits of taking AUGMENTIN tablets during pregnancy or while you are breast-feeding. AUGMENTIN tablets can pass to your baby from breast milk.

- * you have any kidney or liver problems.

The dosage of AUGMENTIN tablets may need to be changed or you may need to be given an alternative medicine.

- * you have to test your urine for sugar.

AUGMENTIN tablets may affect the results of these tests.

- * Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. In particular tell your doctor or pharmacist if you are taking any of the following:

- medicines used to treat gout (eg. probenecid or allopurinol).
- other antibiotics. These may interfere with the actions of AUGMENTIN tablets.
- the contraceptive pill. As with other antibiotics, you may need to use extra birth control methods (eg. condoms) while taking AUGMENTIN tablets.

- * Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when taking AUGMENTIN tablets with other medicines.

How to take AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets

Follow the directions given to you by your doctor and pharmacist. Their directions may differ from the information contained in this leaflet.

Please read the direction label carefully. If you have any concerns about how to take this medicine talk to your doctor or pharmacist.

How much to take:

Take as directed by your doctor or pharmacist.

The usual dose of AUGMENTIN DUO and AUGMENTIN DUO FORTE is one tablet twice a day.

How to take it:

Swallow the AUGMENTIN tablet with a full glass of water or other liquid. AUGMENTIN DUO FORTE tablets can be broken in half, but should not be chewed.

AUGMENTIN tablets should be taken immediately before or with the first mouthful of food. AUGMENTIN tablets work best when taken this way. It may also help to prevent stomach upsets. However, AUGMENTIN tablets will still work if they are taken without food.

Space the doses as evenly as possible throughout the day. If you are taking AUGMENTIN tablets twice a day, take a dose about every twelve hours.

How long to take it for:

Keep taking AUGMENTIN tablets until the course is finished or for as long as your doctor tells you.

Do not stop taking AUGMENTIN tablets just because you feel better as the infection can return.

Do not stop taking, or change the dose without first checking with your doctor.

If you forget to take it:

If your next dose is due within six hours, skip the dose you missed and take your next dose at the normal time. Otherwise, take the missed dose as soon as you remember and then go back to taking your tablets as directed by your doctor.

Do not take a double dose to make up for the dose that you have missed.

Taking more than the prescribed dose can increase the chance of unwanted side-effects.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much, even if there are no signs of discomfort or poisoning.

Symptoms of overdose include mild to severe nausea, vomiting, cramps and diarrhoea.

If you are not sure what to do, contact your doctor, pharmacist or nearest hospital. Be sure to show the doctor the AUGMENTIN DUO or AUGMENTIN DUO FORTE pack.

While you are taking AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets

Things you must do:

Take AUGMENTIN tablets exactly as your doctor has prescribed.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed. Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Tell your doctor, dentist or pharmacist you are taking AUGMENTIN tablets before starting any other medicines. Some medicines may affect the way other medicines work.

Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting AUGMENTIN tablets.

Things you must not do:

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use to treat any other complaints unless your doctor says to.

Things to be careful of:

Be careful drinking alcohol when you are taking AUGMENTIN tablets. Drinking alcohol while taking these tablets does not usually cause any problems. However, some people who drink alcohol while taking antibiotics similar to AUGMENTIN tablets have experienced adverse effects.

Be careful driving or operating machinery until you know how AUGMENTIN tablets affect you. Generally, these tablets do not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, AUGMENTIN tablets may cause dizziness or tiredness in some people.

If you develop severe diarrhoea either when taking AUGMENTIN tablets or within several weeks after treatment, tell your doctor as soon as possible. Do not take any medication to stop the diarrhoea (eg. Lomotil or Imodium).

What are the side-effects?

Check with your doctor as soon as possible if you think you are experiencing any side-effects or allergic reactions due to taking AUGMENTIN tablets, even if the problem is not listed below.

Like other medicines, AUGMENTIN can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Tell your doctor about any effect which is troublesome or ongoing.

MILD EFFECTS

- * **Tell your doctor if you notice any of the following that are troublesome or ongoing:**
 - diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick
 - white, furry, sore tongue and mouth (oral thrush), abnormal taste
 - soreness or itching of the vagina or vaginal discharge (vaginal thrush)
 - headache, dizziness, tiredness, hot flushes
 - tooth discolouration

MORE SERIOUS EFFECTS

- * **Tell your doctor immediately if you notice any of the following during or after taking AUGMENTIN tablets:**
 - itching, rash
 - dark urine or pale stools
 - yellowing of the skin or eyes (jaundice)
 - severe stomach cramps
 - severe watery or bloody diarrhoea
 - unusual bleeding or bruising

These may be symptoms of rare but serious side-effects and require urgent medical attention.

* **Stop taking AUGMENTIN tablets and immediately contact your doctor or go to the emergency department of your nearest hospital if any of the following happens:**

- Wheezing, hives, severe skin reaction, fainting, swelling of limbs, face, lips, mouth or throat, difficulty swallowing or breathing.

These are signs of a severe allergic reaction to AUGMENTIN tablets.

- Allergy to these antibiotics is rare.

- Fits/seizures.

* **Rare events that have been reported with AUGMENTIN DUO AND AUGMENTIN DUO FORTE tablets include:**

- inflammation of the bowel (colitis)
- inflammation of the liver (hepatitis)
- inflammation of the kidney (nephritis)
- blood disorders

Remember, you should tell your doctor or pharmacist as soon as possible if any of these, or any other unusual events or problems occur during or after treatment with AUGMENTIN DUO and AUGMENTIN DUO FORTE TABLETS.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor or pharmacist if you notice any side-effects from your medicine which are not mentioned here.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

How do I store AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets?

Keep your tablets in the original pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

Keep the pack in a cool dry place. Do not leave it in the car on a hot day. Do not store medicine in the bathroom or near a sink. Heat and dampness can destroy AUGMENTIN tablets.

Store all medicines out of the reach of children, such as in a locked cupboard.

If your doctor tells you to stop taking AUGMENTIN tablets or if the expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product description

What they look like:

AUGMENTIN DUO tablets come as white to off white oval shaped tablets containing 500mg of amoxicillin and 125mg of clavulanic acid. The tablet is debossed with 'AC' and a score line on one side and plain on the other side.

AUGMENTIN DUO FORTE tablets come as white to off-white capsule shaped tablets containing 875mg of amoxicillin and 125mg of clavulanic acid. The tablet is marked AUGMENTIN with an A and a C on both sides and a breakline on one side.

Other ingredients:

AUGMENTIN DUO tablets contain the following inactive ingredients: magnesium stearate, sodium starch glycollate, silica colloidal anhydrous and microcrystalline cellulose. The coating on the tablets contains the

colouring agent titanium dioxide, hypromellose 5cps, hypromellose 15 cps, Macrogol 4000, Macrogol 6000 and dimethicone 500.

AUGMENTIN DUO FORTE tablets contain the following inactive ingredients: magnesium stearate, sodium starch glycollate, silica colloidal anhydrous and microcrystalline cellulose. The coating on the tablets contains the colouring agent titanium dioxide, hypromellose 5 & 15 cps, and macrogol 4000 and macrogol 6000.

AUGMENTIN DUO AND AUGMENTIN DUO FORTE tablets do not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

AUGMENTIN DUO AND AUGMENTIN DUO FORTE tablets are available only with a doctor's prescription.

AUGMENTIN DUO tablets come in blister packs of ten tablets.

(AUST R 142692).

AUGMENTIN DUO FORTE tablets come in blister packs of ten tablets.

(AUST R 54900).

Supplier

Your AUGMENTIN DUO and AUGMENTIN DUO FORTE tablets are supplied by:

GlaxoSmithKline Australia Pty Ltd

1061 Mountain Highway

Boronia

Victoria, 3155

Australia.

Tel: (03) 9721 6000

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on

the treatment of your condition.

The information provided applies only to: AUGMENTIN DUO and AUGMENTIN DUO FORTE tablets.

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