AUGMENTIN DUO & AUGMENTIN DUO FORTE tablets

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets?

AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets contains the active ingredients amoxicillin and clavulanic acid. AUGMENTIN tablets are used for the short term treatment of a wide range of infections caused by bacteria.

For more information, see Section 1. Why am I using AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets? in the full CMI.

2. What should I know before I use AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets?

Do not use if you have ever had an allergic reaction to amoxicillin trihydrate, potassium clavulanate, penicillin or similar types of antibiotics (such as cephalosporins), or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use 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.

More instructions can be found in Section 4. How to take AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets? in the full CMI.

5. What should I know while using AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets?

Things you should 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. Remind any doctor, dentist or pharmacist you visit that you are using AUGMENTIN tablets. 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 should 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.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how AUGMENTIN tablets affects you.
Drinking alcohol	Alcohol should be avoided during and for several days after treatment with AUGMENTIN tablets.
Looking after your medicine	 Keep your tablets in the original pack until it is time to take them. Store it in a cool dry place away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while using [insert medicine]? in the full CMI.

6. Are there any side effects?

The most common side effects of AUGMENTIN tablets are diarrhoea, nausea and vomiting. For more information, including what to do if you have any side effects, see Section <u>6</u>. Are there any side effects? in the full CMI.

AUGMENTIN DUO & AUGMENTIN DUO FORTE tablets

Active ingredients: amoxicillin trihydrate & potassium clavulanate

Consumer Medicine Information (CMI)

This leaflet provides important information about using AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets.

Where to find information in this leaflet:

- 1. Why am I using AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets?
- 2. What should I know before I use AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets?
- 3. What if I am taking other medicines?
- 4. How do I use AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets?
- 5. What should I know while using AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets?

AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets contains 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 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.

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

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.

2. What should I know before I use AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets?

Warnings

Do not use AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets if:

- you are allergic to amoxicillin trihydrate, potassium clavulanate, penicillin or similar types of antibiotics (such as cephalosporins), or any of the ingredients 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.

Always check the ingredients to make sure you can use this medicine.

Do not give this medicine to anyone else; your doctor has prescribed it specifically for you and your condition.

Check with your doctor if you:

- have ever had an allergic reaction (such as a rash) to antibiotics or other substances in the past.
- are allergic to foods, dyes, preservatives or any other medicines.
- have experienced liver problems after taking AUGMENTIN tablets or any other medicines.
- have glandular fever (mononucleosis) or leukaemia.
- 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.
- have to test your urine for sugar.
 AUGMENTIN tablets may affect the results of these tests.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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:

- warfarin or other medicines used to prevent blood clots
- mycophenolate.
- medicines used to treat gout (e.g. probenecid or allopurinol).
- other antibiotics. These may interfere with the actions of AUGMENTIN tablets.
- methotrexate (a medicine used to treat cancer or rheumatic diseases.
- contraceptive pill. As with other antibiotics, you may need to use extra birth control methods (e.g. condoms) while taking AUGMENTIN tablets.

Some medicines may interfere with AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets and affect how it works. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets.

4. How do I use 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

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 AUGMENTIN tablets, or change the dose, without first checking with your doctor.

If you forget to take AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets

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

If you use too much AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets

If you think that you have used too much AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets?

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

Remind any doctor, dentist or pharmacist you visit that you are using AUGMENTIN tablets before starting any other medicines. Some medicines may affect the way other medicines work.

Things you should 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

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®).

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets affects 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.

Drinking alcohol

Alcohol should be avoided during and for several days after treatment with AUGMENTIN tablets. Some people who drink alcohol while taking antibiotics similar to AUGMENTIN tablets have experienced adverse effects.

Looking after your medicine

Keep your tablets in the original pack until it is time to take them.

Store it in a cool, dry place where the temperature stays below 25°C, away from moisture, heat or sunlight. Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick nausea, vomiting 	Speak to your doctor if you have any of these less serious side

- 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
- unusually active (hyperactivity)

effects and they worry you.

Serious side effects

Serious side effects	What to do
 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 Rare events: inflammation of the bowel (colitis) inflammation of the liver (hepatitis) inflammation of the kidney (nephritis) blood disorders crystals in the urine (crystalluria). 	Tell your doctor immediately if you notice any of these symptoms during or after taking AUGMENTIN tablets.
 Fits/seizures aseptic meningitis a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck Allergic reactions: Wheezing, hives, severe skin reaction, fainting, swelling of limbs, face, lips, mouth or throat, difficulty swallowing or breathing, joint discomfort or swelling, swollen lymph glands, nausea and vomiting or fever. 	Stop taking AUGMENTIN tables and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What AUGMENTIN tablets contain

Active ingredient	AUGMENTIN DUO tablets:
(main ingredient)	amoxicillin 500 mg clavulanic acid 125 mg
	AUGMENTIN DUO FORTE tablets:
	amoxicillin 875 mg clavulanic acid 125 mg
Other ingredients	magnesium stearate
(inactive ingredients)	sodium starch glycollate
	colloidal anhydrous silica
	microcrystalline cellulose
	The coating on the tablets contains the colouring agent titanium dioxide, hypromellose, propylene glycol, purified talc, and ethylcellulose.

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

Do not take this medicine if you are allergic to any of these ingredients.

What AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets looks like

AUGMENTIN DUO tablets are white capsule shaped tablets debossed with '106' on one side and plain on the other side. AUGMENTIN DUO tablets come in blister packs of ten tablets (AUST R 406956).

AUGMENTIN DUO FORTE tablets are white capsule shaped tablets debossed with 'I 07' on one side and plain on the other side. AUGMENTIN DUO FORTE tablets come in blister packs of ten tablets (AUST R 406957).

Who distributes AUGMENTIN DUO or AUGMENTIN DUO FORTE tablets

Aspen Pharmacare Australia Pty Ltd 34-36 Chandos Street St Leonards NSW 2065 Australia

This leaflet was revised in February 2024.