

AUGMENTIN DUO 400 Suspension

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 my child is using AUGMENTIN DUO 400 Suspension?

AUGMENTIN DUO 400 Suspension contains the active ingredients amoxicillin and clavulanic acid. AUGMENTIN DUO 400 Suspension is 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.

For more information, see Section [1. Why my child is using AUGMENTIN DUO 400 Suspension?](#) in the full CMI.

2. What should I know before giving my child AUGMENTIN DUO 400 Suspension?

Do not use if your child has ever had an allergic reaction to amoxicillin, clavulanic acid, other penicillin based antibiotics or similar antibiotics (such as cephalosporins) or any of the ingredients listed at the end of the CMI.

Talk to your doctor if your child has any other medical conditions, takes any other medicines, or is pregnant or plans to become pregnant or is breastfeeding.

For more information, see Section [2. What should I know before giving my child AUGMENTIN DUO 400 Suspension?](#) in the full CMI.

3. What if my child is taking other medicines?

Some medicines may interfere with AUGMENTIN DUO 400 Suspension and affect how it works.

A list of these medicines is in Section [3. What if my child is taking other medicines?](#) in the full CMI.

4. How to give AUGMENTIN DUO 400 Suspension?

- Always use this medicine exactly as the doctor or pharmacist has told you to.
- The usual dose of this medicine is one dose taken twice a day. The dose may vary depending on your child's weight.

More instructions can be found in Section [4. How to give AUGMENTIN DUO 400 Suspension?](#) in the full CMI.

5. What should I know while giving AUGMENTIN DUO 400 Suspension?

Things you should do	<ul style="list-style-type: none">• Tell your doctor, if, for any reason, your child has not taken this medicine exactly as directed.• Remind any doctor, dentist or pharmacist your child visits that your child is using AUGMENTIN DUO 400 Suspension.• If your child is about to be started on any new medicines, tell the doctor or pharmacist that your child is taking AUGMENTIN DUO 400 Suspension.
Things you should not do	<ul style="list-style-type: none">• Do not use this medicine to treat any other complaints unless your child's doctor says to.• Do not give this medicine to anyone else, even if their symptoms seem similar to your child's.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how AUGMENTIN DUO 400 Suspension affects you.
Looking after your medicine	<ul style="list-style-type: none">• 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.

For more information, see Section [5. What should I know while giving AUGMENTIN DUO 400 Suspension?](#) in the full CMI.

6. Are there any side effects?

Side effects includes diarrhoea, thrust, nausea, vomiting, dizziness, headache, indigestion, skin rash, and itching. Serious side effects includes severe allergic reactions, skin reactions, yellowing of skin/eyes (liver problems), and severe diarrhoea.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

AUGMENTIN DUO 400 Suspension

Active ingredients: amoxicillin trihydrate & potassium clavulanate

Consumer Medicine Information (CMI)

This leaflet provides important information about using AUGMENTIN DUO 400 Suspension. **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 400 Suspension.**

Where to find information in this leaflet:

[1. Why my child is using AUGMENTIN DUO 400 Suspension?](#)

[2. What should I know before giving my child AUGMENTIN DUO 400 Suspension?](#)

[3. What if my child is taking other medicines?](#)

[4. How to give AUGMENTIN DUO 400 Suspension?](#)

[5. What should I know while giving AUGMENTIN DUO 400 Suspension?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why my child is using AUGMENTIN DUO 400 Suspension?

AUGMENTIN DUO 400 Suspension contains two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid. AUGMENTIN DUO 400 Suspension belongs to the penicillin group of antibiotics.

AUGMENTIN DUO 400 Suspension is 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.

AUGMENTIN DUO 400 Suspension works by killing the bacteria that cause these infections.

AUGMENTIN DUO 400 Suspension is used for the treatment of the infections listed. However, the doctor may prescribe these medicines for another use. If you want more information ask the doctor.

There is no evidence that AUGMENTIN DUO 400 Suspension is addictive.

2. What should I know before giving my child AUGMENTIN DUO 400 Suspension?

Warnings

Do not use AUGMENTIN DUO 400 Suspension if:

- your child is allergic to amoxicillin, clavulanic acid, other penicillin based antibiotics or similar antibiotics (such as cephalosporins) or any of the ingredients listed at the end of this leaflet. If your child has ever had an

allergic reaction (such as a rash) when taking an antibiotic you should tell the doctor before any AUGMENTIN DUO 400 Suspension is given.

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

- your child has previously experienced liver problems or jaundice when taking an antibiotic or any other medicines.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

This medicine is for the person named by the doctor. Do not give this medicine to anyone else.

Check with your doctor if your child:

- has ever had an allergic reaction (such as a rash) to any antibiotics or medicines in the past
 - is allergic to foods, dyes, preservatives or any other medicines.
 - has glandular fever (mononucleosis) or a blood disorder.
 - has liver or kidney problems. *The dosage of AUGMENTIN DUO 400 SUSPENSION may need to be changed or your child may need to be given an alternative medicine.*
 - Is not urinating regularly or not able to drink very much.
 - has phenylketonuria. **AUGMENTIN DUO 400 Suspension contains aspartame.**
 - is required to have urine glucose (sugar) test.
- This medicine may affect the results of these tests.

AUGMENTIN DUO 400 Suspension 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 giving this medicine to your child to help reduce the risk of any problems.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

If your child is pregnant or intend to become pregnant, do not take this medicine without checking with your doctor.

Before taking this medicine, talk to your doctor if your child is breastfeeding or intend to breastfeed.

Your doctor will consider the risks-and-benefits of this treatment.

3. What if my child is taking other medicines?

Tell your doctor or pharmacist if you are giving your child 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 the doctor if your child is taking any of the following:

- warfarin or other anticoagulants used to prevent blood clots
- mycophenolate
- medicines used to treat gout (e.g. probenecid or allopurinol)
- methotrexate
- other antibiotics
- 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.

These may affect how AUGMENTIN DUO 400 Suspension works or make it more likely that your child will have side effects.

Some medicines may interfere with AUGMENTIN DUO 400 Suspension 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 400 Suspension.

4. How to give AUGMENTIN DUO 400 Suspension?

Always follow the directions given to you by the doctor or 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 give this medicine, talk to the doctor or pharmacist.

How much to give

- give this medicine as directed by the doctor or pharmacist
- the usual dose of this medicine is one dose taken twice a day. The dose may vary depending on your child's weight.

How to give it

- shake the suspension well before measuring out the dose in a suitable measure. Make sure the whole dose is swallowed each time.
- AUGMENTIN DUO 400 Suspension should be taken immediately before or with the first mouthful of food. This medicine works best when taken this way. It may also help to prevent stomach upsets. However, AUGMENTIN DUO 400 Suspension will still work if taken without food.

- Space the doses as evenly as possible throughout the day. If your child is taking AUGMENTIN DUO 400 Suspension twice a day, give a dose about every twelve hours.

If you forget to give AUGMENTIN DUO 400 Suspension

Give the missed dose as soon as you remember. Then give the next dose at the time it is normally due. Do not give two doses within six hours of each other.

Do not give a double dose to make up for the dose you missed.

If your child takes too much AUGMENTIN DUO 400 Suspension

If you think that your child has used too much AUGMENTIN DUO 400 Suspension, you may need urgent medical attention.

You should immediately:

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

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

5. What should I know while giving AUGMENTIN DUO 400 Suspension?

Things you should do

Tell your doctor if, for any reason, your child has not taken this medicine exactly as directed. Otherwise, your doctor may think that it was not effective and change your child's treatment unnecessarily.

If your child is about to be started on any new medicines, tell the doctor or pharmacist that your child is taking AUGMENTIN DUO 400 suspension.

Call your doctor straight away if your child:

- develops itching, swelling or a skin rash while taking AUGMENTIN DUO 400 Suspension, do not give any more this medicine.
- develops severe diarrhoea either while taking this medicine or within several weeks after treatment. Do not give any medication to stop the diarrhoea (eg Lomotil® or Imodium®).

Remind any doctor, dentist or pharmacist your child visits that your child is using AUGMENTIN DUO 400 Suspension.

Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to your child's.
- Do not use this medicine to treat any other complaints unless your child's doctor says to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AUGMENTIN DUO 400 Suspension affects you.

Looking after your medicine

Do not keep the bottle of AUGMENTIN DUO 400 Suspension longer than 7 days after it has been made up and store in the fridge between 2°C and 8°C. Do not freeze.

Do not store it:

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

Keep out of the sight and reach of children.

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 your child does 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
<ul style="list-style-type: none">• diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick• soreness of the mouth or tongue, abnormal taste, white or furry tongue (oral thrush) or itching of the vagina and/or discharge (vaginal thrush)• headache, dizziness, tiredness, hot flushes• unusually active (hyperactivity)	Speak to your doctor if your child has any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• itching, rash• yellowing of the skin or eyes• dark urine or pale stools• severe diarrhoea• unusual bleeding or bruising• collapse• aseptic meningitis	Call your doctor straight away, or go straight to the Emergency Department at your nearest

<ul style="list-style-type: none">• sign of allergic reaction including wheezing, fainting, swelling of the lips/mouth, difficulty in breathing or swallowing, hayfever, lumpy rash (hives), joint discomfort or swelling, swollen lymph glands, nausea, chest pain, stomach pain, abnormal drowsiness, low blood pressure, repetitive vomiting or fever.	hospital if you notice any of these serious side effects.
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Tell your doctor or pharmacist if you notice anything else that may be making your child feels unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects your child experiences, 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 giving any of your child's medicines.

7. Product details

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

What AUGMENTIN DUO 400 Suspension contains

Active ingredients (main ingredient)	<ul style="list-style-type: none">• amoxicillin trihydrate• potassium clavulanate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• aspartame• colloidal anhydrous silica• Golden Syrup Flavor 501118 AP0551• Hypromellose• Orange DC100 Flavour (DC50100)• Raspberry DC107 Flavour (DC50107)• silicon dioxide• succinic acid• xanthan gum

AUGMENTIN DUO 400 Suspension does 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 400 Suspension looks like

AUGMENTIN DUO 400 Suspension is available as an off-white sugar free suspension containing 400 mg of

amoxicillin and 57 mg of clavulanic acid in each 5ml. Augmentin DUO 400 comes in a glass bottle containing powder for preparing 60 mL of Suspension (AUST R 67352).

Who distributes AUGMENTIN DUO 400 Suspension

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

This leaflet was prepared in September 2023.