

# 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 (as amoxicillin trihydrate) and clavulanic acid (as potassium clavulanate). 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?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor, if, for any reason, your child has not taken this medicine exactly as directed.</li><li>• If your child is about to be started on any new medicines, tell the doctor, dentist or pharmacist that your child is taking AUGMENTIN DUO 400 suspension.</li><li>• Tell your doctor if your child develops itching, swelling or a skin rash while taking this medicine. If this occurs, do not give any more of this medicine.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use this medicine to treat any other complaints unless your child's doctor says to.</li><li>• Do not give this medicine to anyone else, even if their symptoms seem like your child's.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before the patient drives or use any machines or tools until you know how AUGMENTIN DUO 400 suspension affects them.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Once reconstituted by the pharmacist, the suspension should be stored in a refrigerator (2°C to 8°C). Do not freeze.</li><li>• Dispose of any unused suspension 7 days after reconstitution.</li></ul>

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, thrush, 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 (as amoxicillin trihydrate) & clavulanic acid (as 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.

**Ask your doctor if you have any questions about why AUGMENTIN DUO 400 suspension has been prescribed for you.**

Your doctor may have prescribed this medicine for another use.

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

**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.
- is not urinating regularly or not able to drink very much.
- has phenylketonuria. This is because AUGMENTIN DUO 400 suspension contains aspartame.
- is required to have a 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 give 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.

These include:

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

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?

#### How much to give

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, they 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, dentist or pharmacist that your child is taking AUGMENTIN DUO 400 suspension.
- Tell your doctor if your child develops itching, swelling or a skin rash while taking this medicine.  
If this occurs, do not give any more of this medicine.
- Tell your doctor if your child 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®).

#### Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem like 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 the patient drives or use any machines or tools until you know how AUGMENTIN DUO 400 suspension affects them.

#### Looking after your medicine

The dry powder will be stored at the pharmacy below 25°C. The pharmacist will prepare the suspension for you.

Store the reconstituted suspension in the fridge between 2°C and 8°C. Do not freeze.

Discard any unused contents after 7 days.

Keep out of the sight and reach of children.

## Getting rid of any unwanted medicine

Discard any unused contents after 7 days.

## 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"><li>• diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick</li><li>• soreness of the mouth or tongue, abnormal taste, white or furry tongue (oral thrush) or itching of the vagina and/or discharge (vaginal thrush)</li><li>• headache, dizziness, tiredness, hot flushes</li><li>• unusually active (hyperactivity)</li></ul>	<p><b>Speak to your doctor if your child has any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• itching, rash</li><li>• yellowing of the skin or eyes</li><li>• dark urine or pale stools</li><li>• severe diarrhoea</li><li>• unusual bleeding or bruising</li><li>• collapse</li><li>• aseptic meningitis</li><li>• a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck</li><li>• 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.</li></ul>	<p><b>Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**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](http://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

<b>Active ingredients (main ingredient)</b>	Each 5 mL contains: <ul style="list-style-type: none"><li>• amoxicillin (as amoxicillin trihydrate) 400 mg &amp;</li><li>• clavulanic acid (as potassium clavulanate) 57 mg.</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• aspartame</li><li>• colloidal anhydrous silica</li><li>• golden syrup flavor 501118 AP0551</li><li>• hypromellose</li><li>• orange DC100 flavour (DC50100)</li><li>• raspberry DC107 flavour (DC50107)</li><li>• silicon dioxide</li><li>• succinic acid</li><li>• xanthan gum.</li></ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"><li>• aspartame.</li></ul>

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

### What AUGMENTIN DUO 400 suspension looks like

This medicine is available in a glass bottle containing an off-white free flowing powder for preparing 60 mL of suspension.

Once reconstituted, AUGMENTIN DUO 400 suspension is an off-white, mixed fruit flavoured suspension which slowly deposits a slight white sediment on standing.

Australian Registration number: AUST R 67352.

**Who distributes AUGMENTIN DUO 400  
suspension**

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

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