

AMOXIL Paediatric Drops

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 giving AMOXIL to my child?

AMOXIL contains the active ingredient amoxicillin (as amoxicillin trihydrate). AMOXIL is used to treat a range of infections caused by bacteria.

For more information, see Section [1. Why am I giving AMOXIL to my child?](#) in the full CMI.

2. What should I know before giving AMOXIL?

Do not use if your child has ever had an allergic reaction to AMOXIL or any of the ingredients listed at the end of the CMI.

Talk to your child's doctor if they have any other medical conditions or take any other medicines.

For more information, see Section [2. What should I know before giving AMOXIL?](#) in the full CMI.

3. What if my child is taking other medicines?

Some medicines may interfere with AMOXIL 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 do I give AMOXIL to my child?

- The usual dose of AMOXIL is one dose given three times a day.
- AMOXIL doses should be spaced evenly throughout the day e.g. every eight hours if giving it three times a day.
- The dispensing pharmacist will typically reconstitute the dry powder with 18 mL water to form a suspension. Shake the resulting suspension before use. The dose of AMOXIL Paediatric Drops is drawn up and given using the dosing syringe provided with the medicine. Ensure the whole dose is swallowed each time.
- Keep giving AMOXIL until the course is finished or for as long as your child's doctor tells you.

More instructions can be found in Section [4. How do I give AMOXIL to my child?](#) in the full CMI.

5. What should I know while giving AMOXIL to my child?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist that your child visits that they are using AMOXIL.• Tell your child's doctor if, for any reason, you have not given their medicine exactly as directed.• Tell your child's doctor immediately if they develop severe itching or swelling, a skin rash, or severe diarrhoea.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their symptoms seem similar to your child's.• Do not use AMOXIL to treat any other complaints unless your doctor says to.
Looking after your medicine	<ul style="list-style-type: none">• Store the dry powder and the reconstituted suspension in a cool dry place, away from moisture or heat, where the temperature stays below 25°C.• Discard reconstituted suspension after 14 days.

For more information, see Section [5. What should I know while giving AMOXIL to my child?](#) in the full CMI.

6. Are there any side effects?

Mild side effects of giving AMOXIL include diarrhoea, soreness of the mouth or tongue, or overgrowth of yeast infections (thrush).

Serious side effects include itching; rash; unusual bleeding or bruising; yellowing of the skin or eyes; dark urine or pale stools; difficulty or pain on passing urine; severe diarrhoea, tooth discolouration; excessive abnormal muscle movements; dizziness or convulsions; or a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, or neck. Other serious side effects include an allergic reaction. Signs of this include wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives), or fainting.

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.

AMOXIL Paediatric Drops

Active ingredient: amoxicillin (as amoxicillin trihydrate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using AMOXIL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about giving AMOXIL.**

Where to find information in this leaflet:

- [1. Why am I giving AMOXIL to my child?](#)
- [2. What should I know before giving AMOXIL?](#)
- [3. What if my child is taking other medicines?](#)
- [4. How do I give AMOXIL to my child?](#)
- [5. What should I know while giving AMOXIL to my child?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I giving AMOXIL to my child?

AMOXIL contains the active ingredient amoxicillin (as amoxicillin trihydrate). AMOXIL belongs to a group of antibiotic medicines called penicillins.

AMOXIL is used to treat a range of infections caused by bacteria. These may be infections of the chest (pneumonia), tonsils (tonsillitis), sinuses (sinusitis), urinary and genital tract, skin and fleshy tissues.

AMOXIL works by killing the bacteria that cause these infections.

AMOXIL can also be used to prevent infection.

Ask your doctor if you have any questions about why AMOXIL has been prescribed for your child.

Your child's doctor may have prescribed it for another reason.

2. What should I know before giving AMOXIL?

Warnings

Do not give AMOXIL if:

- your child is allergic to penicillin or similar types of antibiotics such as cephalosporins. If your child has ever had an allergic reaction (such as rash) when taking an antibiotic, you should tell your doctor before any AMOXIL is given.
- your child is allergic to amoxicillin, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn or shows signs of tampering.

Check with your child's doctor if:

- your child has any other medical conditions, especially the following:
 - glandular fever (mononucleosis)
 - blood disorders
 - kidney or liver problems(the dose may need to be changed or your child may need to be given an alternate medicine)
- your child is taking any medicines for any other condition.
- your child has ever had an allergic reaction (such as a rash) to any antibiotics in the past.
- your child has had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.

During treatment, your child 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?](#)

3. What if my child is taking other medicines?

Tell your doctor or pharmacist if your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with AMOXIL and affect how it works. These include:

- medicines used to treat gout e.g. probenecid or allopurinol.
- other antibiotics
- anticoagulants (used to prevent blood clots) such as warfarin
- methotrexate, a medicine used to treat arthritis and some types of cancers.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements your child is taking and if these affect AMOXIL.

AMOXIL may influence the results of some laboratory tests.

4. How do I give AMOXIL to my child?

How much to give

Give AMOXIL as directed by your child's doctor or pharmacist.

The dosage varies widely and depends on the patient, the child's weight, the condition being treated and the response to the treatment.

The usual dose is one dose taken three times a day. The doses should be spaced evenly throughout the day e.g. every eight hours if taking it three times a day.

How to give AMOXIL

Shake the bottle to loosen the powder, before reconstituting with 18 mL of water. Shake well to suspend the powder and before use. Note: This part is typically prepared by the pharmacist prior to dispensing.

The suspension is drawn up and given using the dosing syringe provided with the medicine. Ensure the whole dose is swallowed each time.

For oral use only.

AMOXIL can be given with or without food.

How long to give AMOXIL for

Keep giving AMOXIL to your child until the course is finished or for as long as the doctor tells you.

Do not stop giving AMOXIL just because your child feels better as the infection can return.

Do not stop giving AMOXIL to your child or change the dose without first checking with your child's doctor.

If you forget to give AMOXIL

If you forget to give a dose of AMOXIL, give it as soon as you remember. Then go back to giving it as directed by the doctor.

If it is almost time for your child's next dose, skip the dose you missed and give their next dose when you are meant to.

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

Do not give two doses within an hour or so of each other.

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

If you give too much AMOXIL

If you think that you have given too much AMOXIL, your child 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.

You should do this even if your child shows no signs of discomfort or poisoning.

5. What should I know while giving AMOXIL to my child?

Things you should do

Tell your child's doctor if, for any reason, you have not given the medicine exactly as directed.

Otherwise, your child's doctor may think that it was not working as it should and change your child's treatment unnecessarily.

Tell the doctor or pharmacist your child is taking AMOXIL before giving any other prescribed medicine.

Some medicines may affect the way other medicines work.

Call your doctor straight away if:

- your child develops itching, swelling or a skin rash while taking AMOXIL. Do not give any more AMOXIL.
- your child develops severe diarrhoea while taking AMOXIL. Do not give any medication to stop the diarrhoea (e.g. Lomotil or Imodium).

Remind any doctor, dentist or pharmacist your child visits that they are using AMOXIL.

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 AMOXIL to treat any other complaints unless the doctor says to.

Looking after your medicine

Store the dry powder and the reconstituted suspension in a cool dry place, away from moisture or heat, where the temperature stays below 25°C.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car on a hot day

Heat and dampness can destroy some medicines.

Follow the instructions on the pack on how to take care of your child's medicine properly.

Keep it where young children cannot reach it.

When to discard this medicine

Discard reconstituted suspension after 14 days.

Ask your pharmacist what to do with any doses that are left over.

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 give this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If your child experiences 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, feeling sick or being sick• soreness of the mouth or tongue, abnormal taste, white or furry tongue (thrush)• soreness or itching of the vagina and/or discharge (vaginal thrush)	Speak to your child's doctor if they have 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• unusual bleeding or bruising• yellowing of the skin or eyes• dark urine or pale stools• difficulty or pain on passing urine• severe diarrhoea• excessive abnormal muscle movements• dizziness or convulsions• tooth discolouration• a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck	Tell your child's doctor immediately if they experience any of these serious side effects
Signs of allergic reaction: <ul style="list-style-type: none">• wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting.	STOP giving AMOXIL and contact your child's doctor immediately or go to the emergency department of your nearest hospital if they experience any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making your child feel 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 this medicine to your child.

7. Product details

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

What AMOXIL PAEDIATRIC DROPS contain

Active ingredient (main ingredient)	After reconstitution, each 1 mL contains amoxicillin (as amoxicillin trihydrate) 100 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sodium benzoate• carmellose sodium• crospovidone• xanthan gum• hydrophobic colloidal silica anhydrous• aspartame• magnesium stearate• lemon/peach/strawberry fruit mix flavour PHS – 141289
Potential allergens	<ul style="list-style-type: none">• benzoates

AMOXIL Paediatric Drops is sugar free.

Do not give this medicine if your child is allergic to any of these ingredients.

What AMOXIL look like

AMOXIL Paediatric Drops are a white free flowing powder, which when reconstituted with 18 mL water forms an off-white oral suspension. Available in a pack containing a:

- single, sealed glass bottle containing powder for preparing 20 mL amoxicillin oral suspension;
- dosing syringe.

Australian Registration number:

AMOXIL Paediatric Drops: AUST R 201566

Who distributes AMOXIL

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

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