

AMOXIL(R) PAEDIATRIC PREPARATIONS

Amoxicillin

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you give AMOXIL to your child.

This leaflet answers some common questions about AMOXIL. 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 your child taking AMOXIL against the risks this medicine could have for your child.

AMOXIL must be given to your child as instructed. If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is AMOXIL used for?

AMOXIL contains a penicillin called amoxicillin as the active ingredient.

Amoxicillin belongs to the penicillin group of antibiotics.

AMOXIL is used to treat a range of infections caused by bacteria. These

may be infections of the chest (pneumonia), tonsils (tonsillitis), sinuses (sinusitis), inner ear (otitis media) urinary and genital tract or skin and fleshy tissues.

AMOXIL works by killing the bacteria that cause these infections. AMOXIL can also be used to prevent infection.

Your doctor may have prescribed AMOXIL for another reason.

There is no evidence that AMOXIL is addictive.

Before you give AMOXIL

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 a rash) when taking an antibiotic, tell the doctor before any AMOXIL is given.
- * your child has ever had an allergic reaction to amoxicillin or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- * the expiry date (EXP) printed on the pack has passed.
- * the packaging is torn or shows signs of tampering

Tell your doctor if:

- * your child has ever had an allergic reaction (such as a rash) to any antibiotics in the past.
- * your child has glandular fever (mononucleosis) or a blood disorder.
- * your child has liver or kidney problems. The dosage of AMOXIL may need to be changed or your child may need to be given an alternative medicine.
- * Your child is allergic to foods, dyes, preservatives or any other medicines.
- * Your child is taking any other medicines, including medicines you buy without a prescription. In particular tell the doctor if your child is taking any of the following:

- probenecid or allopurinol.
- other antibiotics.

These may interfere with the actions of AMOXIL.

Some medicines may affect the way other medicines work. The doctor or pharmacist will be able to tell you which medicines are safe to take with AMOXIL.

If you have not told the doctor about any of these things, tell them before you give your child any AMOXIL.

How to give AMOXIL to your child

Follow the doctor's instructions about how and when to give AMOXIL. The doctor will advise how many doses are needed each day, and for how long your child will need to take AMOXIL.

Please read the direction label carefully. If you have any concerns about how to give AMOXIL, talk to the doctor or pharmacist.

How much AMOXIL to give:

Give AMOXIL as directed by your doctor or pharmacist.

The usual dose of AMOXIL is one dose taken three times a day. The dose may vary depending on your child's weight.

How to give AMOXIL:

Shake the syrup well before measuring out the dose in a suitable measure. The dose of AMOXIL Paediatric Drops is drawn up and given using the dropper provided with the medicine. Make sure the whole dose is swallowed each time.

Space the doses as evenly as possible throughout the day. For example, if your child is taking AMOXIL three times a day, give a dose about every eight hours.

AMOXIL can be given with or without food. The effects of AMOXIL are not changed by 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 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.

Do not give a double dose to make up for the dose that has been 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.

What do I do if I give too much AMOXIL? (Overdose)

If your child (or someone else) has taken a large amount of AMOXIL all at once, give plenty of water to drink, and immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much AMOXIL, even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor, pharmacist or nearest hospital.

While you are giving AMOXIL to your child

Things you must do:

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

Otherwise, your 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.

If your child develops itching, swelling or a skin rash while taking AMOXIL, do not give any more AMOXIL and tell the doctor at once.

If your child develops severe diarrhoea while taking AMOXIL tell the doctor as soon as possible. Do not give any medication to stop the diarrhoea (eg. Lomotil or Imodium).

Things you must 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 your doctor says so.

What are the side-effects?

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

Like other medicines, AMOXIL 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.

MILD EFFECTS

- * **Tell the doctor if any of the following are troublesome or ongoing:**
 - diarrhoea (several loose bowel movements per day), indigestion, feeling sick or being sick
 - soreness of the mouth or tongue
 - overgrowth of yeast infections (thrush).

MORE SERIOUS EFFECTS

- * **Tell the doctor immediately if any of the following occur:**
 - 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.
- * **Stop giving AMOXIL and contact the doctor or take your child to the emergency department of the nearest hospital if any of the following happens:**
- Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction.

Remember you should tell the doctor or pharmacist as soon as possible if any of these, or any other unusual events or problems occur during or after your child's treatment with AMOXIL.

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 child's medicine which are not mentioned here.

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

How do I store AMOXIL?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep the bottle in a cool dry place where the temperature stays below 25 degrees C. 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 some medicines.

Do not use any AMOXIL syrup left in the bottle 14 days after opening. Ask your pharmacist what to do with any doses that are left over.

Return any unused or expired medicine to your pharmacist.

Product description

What AMOXIL looks like:

AMOXIL syrups are available as:

- * a yellow or off-white sugar free syrup containing 125mg amoxycillin/5mL (Amoxil Syrup), and
- * a yellow or off-white sugar free syrup containing 250mg amoxycillin/5mL (Amoxil Syrup Forte).

AMOXIL Paediatric Drops are available as:

- * a yellow liquid suspension containing 100mg amoxycillin/mL.

Ingredients:

All AMOXIL preparations contain the active ingredient amoxycillin.

AMOXIL syrups also contain the inactive ingredients disodium edetate, sodium benzoate, saccharin sodium, xanthan gum, colloidal anhydrous silica, silicon dioxide, sorbitol and lemon/peach/strawberry fruit mix flavour PHS-141289.

AMOXIL Paediatric Drops also contain the inactive ingredients sodium benzoate, carmellose sodium, peach trusil flavour (17-3449), strawberry trusil flavour (17-8729), lemon trusil flavour (16-8162) and sucrose.

AMOXIL preparations do not contain lactose, gluten, tartrazine or any other azo dyes.

Supplier:

Your AMOXIL is supplied by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia
Victoria, 3155
Australia.
Tel: (03) 9721 6000

Distributed in New Zealand by:

GlaxoSmithKline NZ Ltd
Auckland
New Zealand

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.

AMOXIL preparations are only available if prescribed by a doctor.

AMOXIL is also available as capsules and injections.

AMOXIL paediatric preparations come in the following packs:

- AMOXIL 125mg/5mL Syrup 100mL (AUST R 11133).
- AMOXIL Forte 250mg/5mL Syrup 100mL (AUST R 11134).
- AMOXIL Paediatric Drops 20mL (AUST R 11132).

The information provided applies only to AMOXIL(R)

(R)AMOXIL is a registered trademark of the GlaxoSmithKline Group of Companies.

This leaflet is subject to copyright.

AMOXIL Paediatric Preparations
Issue 4

Prepared on: 8 November 2007