

Noumed Amoxicillin Oral Suspension

amoxicillin trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Noumed Amoxicillin Oral Suspension.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

The name of your medicine is Noumed Amoxicillin Oral Suspension. It contains the active ingredient amoxicillin trihydrate.

Amoxicillin is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that cause infections.

Noumed Amoxicillin Oral Suspension is used to treat infections in different parts of the body caused by bacteria. These may be infections of the chest (pneumonia), tonsils (tonsillitis),

sinuses (sinusitis), urinary and genital tract, skin and fleshy tissues.

It is also used to prevent infections before, during and after surgery.

Noumed Amoxicillin Oral Suspension will not work against infections caused by viruses such as colds or the flu.

Your doctor may have prescribed this medicine for another reason.

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

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

Noumed Amoxicillin Oral Suspension is not addictive.

Before your child takes this medicine

When your child must not take it

Noumed Amoxicillin Oral Suspension must not be taken if your child has an allergy to:

- amoxicillin
- any β -lactam antibiotics (e.g. penicillins, cephalosporins, carbapenem or monobactam)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether your child should start taking this medicine, talk to your doctor.

Before your child starts to take it

Tell your doctor if:

- 1. you have ever had any allergies to any antibiotics, and other medicines, foods, preservatives or dyes.**
- 2. you are pregnant or intend to become pregnant.**

Your doctor will discuss the possible risks and benefits of using this medicine during pregnancy.

- 3. you are breast-feeding or intend to breast-feed.**

Noumed Amoxicillin passes into breast milk. Your doctor will discuss the risks and benefits of taking this medicine when breastfeeding.

- 4. Tell your doctor if you have or have had any of the following medical conditions:**

- glandular fever (mononucleosis)
- blood disorders
- diabetes
- seizures history

- stomach or bowel problems
- liver or kidney problems
- asthma
- history of allergic problems, including hayfever.

If you have not told your doctor about any of the above, tell them before your child takes this medicine.

Taking other medicines

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

Some medicines may interfere with this medicine. These include:

- medicines used to treat gout (e.g. probenecid or allopurinol)
- digoxin, a medicine used to treat heart failure
- other antibiotics (e.g. tetracyclines)
- anticoagulants (used to prevent blood clots) such as warfarin
- methotrexate, a medicine used to treat arthritis and some types of cancers
- oral contraceptives (birth control pills)

These medicines may be affected by Noumed Amoxicillin Oral Suspension, or may affect how well it works. Your child may need different amounts of the medicine, or may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking Noumed Amoxicillin oral suspension.

How to give this medicine to your child

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to give

The usual dose of Noumed Amoxicillin oral suspension is one dose taken three times a day. The dose may vary according to your child's weight.

How to give it

Shake the suspension well before measuring out the dose in a suitable measure. Make sure that the whole dose is swallowed each time.

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

This medicine can be given with or without food. The effects of this medicine are not changed by food.

How long to take it

Continue giving this medicine to your child until the course is finished or for as long as your doctor recommends.

Do not stop giving this medicine to your child just because he/she feels better.

If the full course prescribed by your doctor is not completed, all of the bacteria causing the infection may not be killed. These bacteria may continue to grow and multiply so that the infection may not clear completely, or it may return.

If you forget to give it

If it is almost time for your child's next dose, skip the missed dose and

give the next dose when you are meant to. Otherwise, give it as soon as you remember, and then go back to giving the doses as you would normally.

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

If you have trouble remembering to give the doses, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that your child or anyone else may have taken too much Noumed Amoxicillin.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If your child takes too much Noumed Amoxicillin, he/she may get diarrhoea and nausea.

While you are giving this medicine

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.

If the symptoms of your child's infection do not improve within a few days, or if they become worse, tell your doctor.

If your child develops itching with swelling or skin rash, or difficulty breathing while taking Noumed Amoxicillin, do not give any more Noumed Amoxicillin and contact your doctor immediately.

If your child gets severe diarrhoea tell your doctor,

pharmacist or nurse immediately. Do this even if it occurs several weeks after Noumed Amoxicillin has been stopped.

Diarrhoea may mean that your child has a serious condition affecting the bowel. They may need urgent medical care.

Do not give any anti-diarrhoea medicine.

If your child gets a sore white mouth or tongue while taking or soon after stopping Noumed Amoxicillin, tell your doctor. Also tell your doctor if your daughter gets vaginal itching or discharge.

This may mean your child has a fungal infection called thrush.

Sometimes the use of amoxicillin allows fungi to grow and the above symptoms to occur. Amoxicillin does not work against fungi.

Tell your doctor or pharmacist if your child's urine has to be tested for sugar levels while taking this medicine.

Amoxicillin will produce false positive results when some of these tests are used. Your doctor will help you identify the correct test.

If your child is about to start taking any new medicine, tell your doctor and pharmacist that he/she is taking Noumed Amoxicillin.

Tell all doctors, dentists and pharmacists who are treating your child that he/she is taking Noumed Amoxicillin.

Things you must not do

Do not give Noumed Amoxicillin to anyone else, even if they have the same condition as your child.

Do not give Noumed Amoxicillin to treat any other complaints unless your doctor tells you to.

Side effects

Check with your doctor as soon as possible if your child has any problems while taking Noumed Amoxicillin, even if you do not

think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Noumed Amoxicillin can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice your child has any of the following and they are troublesome or ongoing:

- soreness of the tongue or mouth
- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina or discharge
- diarrhoea (several loose bowel movements per day), indigestion, feeling sick or being sick
- discoloration of the teeth. Usually the discoloration can be removed by teeth brushing
- headache, tiredness.

These side effects are usually mild.

Tell your doctor immediately if you notice your child has any of the following:

- signs of anaemia such as looking pale, short of breath when exercising, dizziness
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- itching, rash
- unusual bleeding or bruising
- yellowing of the skin or eyes
- dark urine or pale stools
- difficulty or pain on passing urine

These are serious side effects. Your child may need urgent medical attention. Serious side effects are rare.

If any of the following occur, stop giving Noumed Amoxicillin and tell your doctor immediately or go to the Accident and Emergency

department of your nearest hospital:

- wheezing, swelling of the lips/mouth, difficulty in breathing
- any skin rash, itching or hives or blistering or peeling of the skin
- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody.

These are very serious side effects. Your child may need urgent medical attention or hospitalisation. Serious side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making your child feel unwell.

Ask your doctor or pharmacist if you do not understand anything in this list.

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

After giving this medicine

Storage

Keep the Noumed Amoxicillin suspension in the bottle until it is time to give a dose.

If you take the suspension out of the bottle, it may not keep well.

Keep the bottle in the refrigerator (but do not freeze it).

Keep all medicines well out of reach of children.

Do not use any Noumed Amoxicillin suspension left in the bottle after the expiry date printed on the label or pack (the expiry date will be 14 days after the powder is reconstituted to form a suspension by the pharmacist).

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

Disposal

If your doctor tells you to stop giving Noumed Amoxicillin to your child, or it has passed the expiry date, ask your pharmacist what to do with any suspension that is left over.

Product description

What it looks like

Noumed Amoxicillin forms 100 mL of an orange suspension when it is reconstituted by the pharmacist, and is available in the following strengths:

- Noumed Amoxicillin
125 mg/5 mL
- Noumed Amoxicillin
250 mg/5 mL

Ingredients

Noumed Amoxycillin Oral Suspension contains either 125 mg or 250 mg of amoxicillin (as amoxicillin trihydrate) per 5 mL.

Inactive ingredients:

- sorbitol
- sunset yellow FCF CI 15985
- tutti frutti flavour
- xanthan gum
- sodium citrate
- colloidal anhydrous silica
- saccharin sodium

Australian Registration Numbers

- Noumed Amoxicillin
125 mg/5 mL: AUST R 324499
- Noumed Amoxicillin
250 mg/5 mL: AUST R 324500

Sponsor

Avallon Pharmaceuticals Pty Ltd
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