

AUGMENTIN® SYRUP

Amoxicillin and Clavulanic Acid

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you give AUGMENTIN SYRUP.

This leaflet answers some common questions about AUGMENTIN SYRUP. It does not contain all of the available information.

It does not take the place of talking to your child's 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 child's doctor has weighed the expected benefits of your child taking AUGMENTIN SYRUP against the risks this medicine could have for your child.

AUGMENTIN must be given to your child as instructed. If you have any concerns about giving this medicine to your child, ask your child's doctor or pharmacist. Keep this leaflet until your child has finished the course of AUGMENTIN SYRUP.

You may need to read it again.

What is AUGMENTIN SYRUP used for?

AUGMENTIN SYRUP contains two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanate.

AUGMENTIN SYRUP belongs to the penicillin group of antibiotics.

AUGMENTIN SYRUP is used to treat 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 SYRUP works by killing the bacteria that cause these infections.

AUGMENTIN SYRUP is used for the treatment of the infections listed. However the doctor may prescribe this medicine for another use. If you want more information ask the doctor.

Your doctor may have prescribed AUGMENTIN SYRUP for another reason.

There is no evidence that AUGMENTIN SYRUP is addictive.

Before you give AUGMENTIN SYRUP

AUGMENTIN SYRUP must not be given if:

- your child is allergic to penicillin or similar types of antibiotics (such as cephalosporins) or any of the ingredients contained in AUGMENTIN SYRUP. 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 SYRUP is given.
- your child has previously experienced liver problems after taking AUGMENTIN SYRUP 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.

Before your child starts taking AUGMENTIN SYRUP tell the doctor if:

- your child has ever had an allergic reaction (such as a rash) to any antibiotics in the past.
- your child is allergic to foods, dyes, preservatives or any other medicines.
- your child has glandular fever (mononucleosis) or a blood disorder.
- your child has liver or kidney problems. The dosage of AUGMENTIN SYRUP may need to be changed or your child may need to be given an alternative medicine.
- your child's urine has to be tested for sugar. AUGMENTIN SYRUP may affect the results of these tests.
- 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.
 - warfarin or other medicines used to prevent blood clots
 - mycophenolate
 - other antibiotics. These may interfere with the actions of AUGMENTIN SYRUP.

Some medicines may affect the way other medicines work. Your child's doctor or pharmacist will be able to tell you which medicines are safe to take with AUGMENTIN SYRUP.

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

How to give AUGMENTIN SYRUP to your child

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

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

How much to give:

Give AUGMENTIN SYRUP as directed by the doctor or pharmacist.

The usual dose of AUGMENTIN SYRUP is one dose taken three times 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 SYRUP should be taken immediately before or with the first mouthful of food. AUGMENTIN SYRUP works best when taken this way. It may also help to prevent stomach upsets. However, AUGMENTIN SYRUP will still work if taken without food. Space the doses as evenly as possible throughout the day. If your child is taking AUGMENTIN

SYRUP three times a day, give a dose about every eight hours.

How long to give it for:

Keep giving AUGMENTIN SYRUP until the course is finished or for as long as the doctor advised. Do not stop giving AUGMENTIN SYRUP just because your child feels better as the infection can return.

Do not stop giving AUGMENTIN SYRUP or change the dose without first checking with the doctor.

If you forget to give it:

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 four hours of each other.

Do not try to make up for missed doses by giving more than one dose at a time. Giving more than the prescribed dose can increase the chance of unwanted side-effects.

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

Immediately telephone the doctor or Poisons Information Centre (telephone 131126) for advice if you think your child or anyone else may have taken too much AUGMENTIN SYRUP, even if there are no signs of discomfort or poisoning.

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

While you are giving AUGMENTIN SYRUP

Things you must do:

Tell the doctor if, for any reason, you have not given your medicine exactly as directed. Otherwise, the 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 AUGMENTIN SYRUP, 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 AUGMENTIN SYRUP, do not give any more AUGMENTIN SYRUP and tell the doctor immediately.

If your child develops severe diarrhoea either while taking AUGMENTIN SYRUP or within several weeks after treatment, 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 AUGMENTIN SYRUP to treat any other complaints unless your child's doctor says to.

What are the side-effects?

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

Like other medicines, AUGMENTIN SYRUP 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. Tell the doctor about any effect which is troublesome or ongoing.

- **Tell the doctor if you notice any of the following are troublesome or ongoing:**
 - 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).
- headache, dizziness, tiredness, hot flushes.

- soreness or itching of the vagina and/or discharge (vaginal thrush).

- unusually active (hyperactivity)

- **Tell your child's doctor immediately if you notice any of the following:**

- itching, rash
- yellowing of the skin or eyes
- dark urine or pale stools
- severe diarrhoea
- unusual bleeding or bruising

- **Stop giving AUGMENTIN SYRUP and contact the doctor or take your child to the emergency department of the nearest hospital if any of the following happens:**

- Wheezing, fainting, swelling of the lips/mouth, difficulty in breathing or swallowing, hayfever, lumpy rash (hives) joint discomfort or swelling, swollen lymph glands, nausea and vomiting or fever. These could be symptoms of an allergic reaction or other reaction.

- **Rare events that have been reported with AUGMENTIN SYRUP include:**

- inflammation of the bowel (colitis)
- inflammation of the liver or kidney
- blood disorders
- crystals in the urine (crystalluria)

Remember you should tell the doctor or pharmacist as soon as possible if any of these, or any other unusual events or problems which are not mentioned here, occur during or after treatment with AUGMENTIN SYRUP.

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.

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

How do I store AUGMENTIN SYRUP?

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

Keep the bottle in the refrigerator where the temperature stays between 2 and 8°C. Heat can destroy AUGMENTIN SYRUP.

Do not leave in a car, on a window sill or in the bathroom.

Do not use any suspension left in the bottle 7 days after collecting from the pharmacy. Ask your pharmacist what to do with any doses that are left over.

Product description

What AUGMENTIN SYRUP looks like:

AUGMENTIN SYRUP is available as:

- an off-white sugar free syrup containing 125 mg of amoxicillin and 31.25mg of clavulanate in each 5mL, in bottles of 75mL.

Other Ingredients

AUGMENTIN syrup contains the following inactive ingredients: xanthan gum, aspartame, colloidal anhydrous silica, silicon dioxide, succinic acid, hypromellose and mixed fruit flavour.

AUGMENTIN syrup does not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

Supplier:

Your AUGMENTIN SYRUP is supplied by:

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

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your child's doctor or pharmacist is the best person to give you advice on the treatment of your condition.

The information provided applies only to AUGMENTIN SYRUP

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