

GA-AMCLAV 125/31.25 SYRUP

Amoxicillin (as trihydrate) and Clavulanic Acid (as potassium clavulanate)

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you give GA-Amclav 125/31.25 syrup.

This leaflet answers some common questions about GA-Amclav 125/31.25 syrup. 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 GA-Amclav 125/31.25 syrup against the risks this medicine could have for your child.

GA-Amclav 125/31.25 must be given to your child as instructed. If you have any concerns about giving this medicine to your child, ask your doctor or pharmacist.

Keep this leaflet until your child has finished the course of GA-Amclav 125/31.25 syrup.

You may need to read it again.

What is GA-Amclav 125/31.25 syrup used for?

GA-Amclav 125/31.25 syrup contains two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanate. GA-Amclav 125/31.25 syrup belongs to the penicillin group of antibiotics.

GA-Amclav 125/31.25 syrup is used to treat a wide range of infections caused by bacteria. These infections may affect the chest (bronchitis or pneumonia), bladder (cystitis), sinuses (sinusitis), the ears (otitis media) or the skin.

GA-Amclav 125/31.25 syrup works by killing the bacteria that cause these infections.

GA-Amclav 125/31.25 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 GA-Amclav 125/31.25 syrup for another reason.

There is no evidence that GA-Amclav 125/31.25 syrup is addictive.

Before you give GA-Amclav 125/31.25 syrup

GA-Amclav 125/31.25 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 GA-Amclav 125/31.25 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 GA-Amclav 125/31.25 syrup is given.

- your child has previously experienced liver problems after taking GA-Amclav 125/31.25 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 GA-Amclav 125/31.25 syrup tell your 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 GA-Amclav 125/31.25 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. GA-Amclav 125/31.25 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.
 - other antibiotics. These may interfere with the actions of GA-Amclav 125/31.25 syrup.

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you which medicines are safe to take with GA-Amclav 125/31.25 syrup.

If you have not told your doctor about any of these things, tell them before you give your child any GA-Amclav 125/31.25 syrup.

How to give GA-Amclav 125/31.25 syrup to your child

Follow your doctor's instructions about how and when to give GA-Amclav 125/31.25 syrup. Your doctor will advise how many doses are needed each day, and for how long your child will need to take GA-Amclav 125/31.25 syrup.

Please read the direction label carefully. If you have any concerns about how to give GA-Amclav 125/31.25 syrup talk to your doctor or pharmacist.

How much to give:

Give GA-Amclav 125/31.25 syrup as directed by your doctor or pharmacist.

The usual dose of GA-Amclav 125/31.25 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.

GA-Amclav 125/31.25 syrup should be taken immediately before or with the first mouthful of food. GA-Amclav 125/31.25 syrup works best when taken this way. It may also help to prevent stomach upsets. However, GA-Amclav 125/31.25 syrup will still work if taken without food.

Space the doses as evenly as possible throughout the day. If your child is taking GA-Amclav 125/31.25 syrup three times a day, give a dose about every eight hours.

How long to give it for:

Keep giving GA-Amclav 125/31.25 syrup until the course is finished or for as long as your doctor advised. Do not stop giving GA-Amclav 125/31.25 syrup just because your child feels better as the infection can return.

Do not stop giving GA-Amclav 125/31.25 syrup, or change the dose without first checking with your 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 your doctor or Poisons Information Centre (telephone 131126) for advice, if you think your child or anyone else may have taken too much GA-Amclav 125/31.25 syrup, 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 GA-Amclav 125/31.25 syrup

Things you must do:

Tell your doctor if, for any reason, you have not given your 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 GA-Amclav 125/31.25 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 GA-Amclav 125/31.25 syrup, do not give any more GA-Amclav 125/31.25 syrup and tell the doctor at once.

If your child develops severe diarrhoea either while taking GA-Amclav 125/31.25 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 GA-Amclav 125/31.25 syrup to treat any other complaints unless your doctor says to.

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 GA-Amclav 125/31.25 syrup, even if the problem is not listed below.

Like other medicines, GA-Amclav 125/31.25 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, "hairy" tongue.
- headache, dizziness, tiredness, hot flushes.
- overgrowth of yeast infections (thrush).

Tell your 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 GA-Amclav 125/31.25 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) or fainting. These could be symptoms of an allergic reaction.

Rare events that have been reported with GA-Amclav 125/31.25 syrup include:

- inflammation of the bowel (colitis)
- inflammation of the liver or kidney
- blood disorders

Remember you should tell your 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 GA-Amclav 125/31.25 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 GA-Amclav 125/31.25 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 GA-Amclav 125/31.25 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 GA-Amclav 125/31.25 syrup looks like:

GA-Amclav 125/31.25 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

GA-Amclav 125/31.25 syrup contains the following inactive ingredients: xanthan gum, aspartame, silica colloidal anhydrous, silicon dioxide, succinic acid, hypromellose and mixed fruit flavour (3824).

GA-Amclav 125/31.25 syrup does not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

Supplier:

Your GA-Amclav 125/31.25 syrup is supplied by:

www.ascentpharma.com.au



Ascent Pharma Pty Ltd

151 - 153 Clarendon Street
South Melbourne VIC 3205

For further information call 1800 554 414.

The information provided applies only to GA-Amclav 125/31.25 syrup

GA-Amclav 125/31.25 :
AUST R 190076.

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