

CLAVULIN(R) DUO 400 SUSPENSION

Amoxicillin and Clavulanic Acid

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you give CLAVULIN DUO 400 SUSPENSION.

This leaflet answers some common questions about CLAVULIN DUO 400 SUSPENSION. 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 CLAVULIN DUO 400 SUSPENSION against the risks this medicine could have for your child.

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

Keep this leaflet until your child has finished the course of CLAVULIN DUO 400 SUSPENSION.

You may need to read it again.

What is CLAVULIN DUO 400 SUSPENSION used for?

CLAVULIN DUO 400 SUSPENSION contains two active ingredients. One of these is a penicillin called amoxicillin and the

other is clavulanate. CLAVULIN DUO 400 SUSPENSION belongs to the penicillin group of antibiotics.

CLAVULIN DUO 400 SUSPENSION 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.

CLAVULIN DUO 400 SUSPENSION works by killing the bacteria that cause these infections.

CLAVULIN DUO 400 SUSPENSION is used for the treatment of the infections listed. However, the doctor may prescribe these medicines for another use. If you want more information ask the doctor.

There is no evidence that CLAVULIN DUO 400 SUSPENSION is addictive.

Before you give CLAVULIN DUO 400 SUSPENSION

CLAVULIN DUO 400 SUSPENSION 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 CLAVULIN DUO 400

SUSPENSION. If your child has ever had an allergic reaction (such as a rash) when taking an antibiotic you should tell the doctor before any CLAVULIN DUO 400 SUSPENSION is given.

- * your child has previously experienced liver problems after taking CLAVULIN DUO 400 SUSPENSION 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 CLAVULIN DUO 400 SUSPENSION 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 CLAVULIN DUO 400 SUSPENSION may need to be changed or your child may need to be given an alternative medicine.

- * your child has phenylketonuria.

CLAVULIN DUO 400 SUSPENSION contains aspartame.

- * your child's urine has to be tested for sugar. CLAVULIN DUO 400 SUSPENSION 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 CLAVULIN DUO 400 SUSPENSION.

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 CLAVULIN DUO 400 SUSPENSION.

If you have not told your doctor about any of these things, tell them before you give your child any CLAVULIN DUO 400 SUSPENSION.

How to give CLAVULIN DUO 400 SUSPENSION to your child

Follow your doctor's instructions about how and when to give CLAVULIN DUO 400 SUSPENSION. Your doctor will advise how many doses are needed each day, and for how long your child will need to take CLAVULIN DUO 400 SUSPENSION.

Please read the direction label carefully. If you have any concerns about how to give CLAVULIN DUO 400 SUSPENSION talk to your doctor or pharmacist.

How much to give:

Give CLAVULIN DUO 400 SUSPENSION as directed by your doctor or pharmacist.

The usual dose of CLAVULIN DUO 400 SUSPENSION is one dose taken twice 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.

CLAVULIN DUO 400 SUSPENSION should be taken immediately before or with the first mouthful of food. CLAVULIN DUO 400 SUSPENSION works best when taken this way. It may also help to prevent stomach upsets. However, CLAVULIN DUO 400 SUSPENSION will still work if taken without food.

Space the doses as evenly as possible throughout the day. If your child is taking CLAVULIN DUO 400 SUSPENSION twice a day, give a dose about every twelve hours.

How long to give it for:

Keep giving CLAVULIN DUO 400 SUSPENSION until the course is finished or for as long as your doctor advised. Do not stop giving CLAVULIN DUO 400 SUSPENSION just because your child feels better as the infection can return.

Do not stop giving CLAVULIN DUO 400 SUSPENSION, 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 six 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)

There are unlikely to be any serious problems following an overdose of CLAVULIN DUO 400 SUSPENSION.

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 CLAVULIN DUO 400 SUSPENSION, 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 CLAVULIN DUO 400 SUSPENSION

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 CLAVULIN DUO 400 SUSPENSION, 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 CLAVULIN DUO 400 SUSPENSION, do not give any more CLAVULIN DUO 400 SUSPENSION and tell the doctor at once.

If your child develops severe diarrhoea either while taking CLAVULIN DUO 400 SUSPENSION 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 CLAVULIN DUO 400 SUSPENSION 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 CLAVULIN DUO 400 SUSPENSION, even if the problem is not listed below.

Like other medicines, CLAVULIN DUO 400 SUSPENSION 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 CLAVULIN DUO 400 SUSPENSION 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 CLAVULIN DUO 400 SUSPENSION 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 CLAVULIN DUO 400 SUSPENSION.

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 CLAVULIN DUO 400 SUSPENSION?

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 degrees C. Heat can destroy CLAVULIN DUO 400 SUSPENSION.

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 CLAVULIN DUO 400 SUSPENSION looks like:

CLAVULIN DUO 400 SUSPENSION is available as an off-white sugar free suspension containing 400 mg of amoxicillin and 57 mg of clavulanate in each 5 mL. CLAVULIN Duo 400 comes in a glass bottle containing powder for preparing 60 mL of suspension.

Other Ingredients:

CLAVULIN DUO 400 SUSPENSION contains the following inactive ingredients: xanthan gum, aspartame, succinic acid, colloidal silica anhydrous, hypromellose 6, silicon dioxide and a mixed fruit flavour.

CLAVULIN DUO 400 SUSPENSION does not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

Supplier:

Your CLAVULIN DUO 400 SUSPENSION is supplied by:

Menley and James
A Division of:
GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia, Victoria, 3155
Australia.

Tel: (03) 9721 6000

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.

The information provided applies only to CLAVULIN DUO 400 SUSPENSION

(R)CLAVULIN is a registered trade mark of the GlaxoSmithKline Group of Companies.

CLAVULIN DUO 400
SUSPENSION AUST R 80626

This leaflet is subject to copyright.

Issue 3

Prepared on 12 June 2007.