

Clamoxyl Duo 400/57 Suspension

contains the active ingredients amoxicillin and clavulanic acid

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Clamoxyl Duo 400/57 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 benefits and risks. Your doctor has weighed the risks of your child taking Clamoxyl Duo 400/57 against the benefits they expect it will have for your child.

If you have any concerns about giving this medicine to your child, talk to your doctor or pharmacist.

Please read this leaflet carefully and keep it with your medicine.

You may need to read it again.

What Clamoxyl Duo 400/57 Suspension is used for

Clamoxyl Duo 400/57 is used to treat certain types of bacterial infections in the body such as:

- * skin infections
- * urinary tract infections, including bladder and kidney infections
- * respiratory tract infections, including infections of the throat, airways, lungs or sinuses
- * middle ear infections

Clamoxyl Duo 400/57 is a medicine that works by killing the bacteria that

cause these infections.

Clamoxyl Duo 400/57 contains two active ingredients. Amoxicillin is an antibiotic that belongs to a group of medicines called penicillins.

Clavulanic acid is used to increase the effectiveness of amoxicillin against certain types of bacteria.

Clamoxyl Duo 400/57 does not work against infections caused by viruses, such as colds or flu, or fungi.

Ask your doctor if you have any questions about why Clamoxyl Duo 400/57 has been prescribed for your child.

Your doctor may have prescribed Clamoxyl Duo 400/57 for another reason.

Clamoxyl Duo 400/57 is available only with a doctor's prescription.

There is no evidence that Clamoxyl Duo 400/57 is addictive.

Before you give Clamoxyl Duo 400/57 Suspension

When you must not give it

Do not give Clamoxyl Duo 400/57 if your child is allergic to:

- * medicines containing amoxicillin or any other penicillin (eg. ampicillin)
- * cephalosporin antibiotics
- * any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips, mouth or throat, which may cause difficulty with swallowing or breathing.

Do not give Clamoxyl Duo 400/57 if your child has ever had liver problems after taking this or any other medicine.

Check with your doctor or pharmacist if you are not sure about any of the above.

Do not give Clamoxyl Duo 400/57 if the expiry date (EXP) printed on the pack has passed.

If you give this medicine after the expiry date, it may not work as well.

Do not give Clamoxyl Duo 400/57 if the packaging shows signs of tampering or the medicine does not look quite right.

Before your child starts to take it

Tell your doctor if your child is allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if your child has, or has had, any other medical conditions, especially the following:

- * glandular fever
- * blood disorders
- * liver problems
- * kidney problems
- * phenylketonuria (Clamoxyl Duo 400/57 Suspension contains aspartame)

The dose of Clamoxyl Duo 400/57 may need to be changed or your child may need to be given another medicine.

If you have not told your doctor about any of the above, tell him/her before you start giving Clamoxyl Duo 400/57 Suspension to your child.

Taking other medicines

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

Some medicines may be affected by Clamoxyl Duo 400/57 or may affect how well it works. These include:

- * probenecid and allopurinol, medicines used to prevent gout
- * certain other antibiotics, including tetracyclines, erythromycin and chloramphenicol

Your doctor can tell you what to do if you are giving your child any of these medicines.

If you are not sure whether you are giving your child any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while giving Clamoxyl Duo 400/57 Suspension.

How to give Clamoxyl Duo 400/57 Suspension to your child

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to give

The dose varies from person to person.

Your doctor will tell you how much Clamoxyl Duo 400/57 you need to give to your child each day.

The usual dose of Clamoxyl Duo 400/57 is one dose taken twice a day.

The dose depends on your child's condition and his/her weight.

How to give it

Shake the bottle well before measuring out the correct dose in a suitable measure.

Make sure that your child swallows the whole dose each time.

When to give it

Give Clamoxyl Duo 400/57 Suspension immediately before or with the first mouthful of food.

Giving Clamoxyl Duo 400/57 in this way increases the effectiveness of this medicine, and also helps prevent stomach upsets.

Give Clamoxyl Duo 400/57 at about the same time each day.

Giving it at the same time each day will have the best effect. It will also help you remember when to give it.

How long to give it for

Keep giving Clamoxyl Duo 400/57 until you finish the bottle, or for as long as your doctor recommends.

Do not stop giving Clamoxyl Duo 400/57 even if your child feels better after a few days, unless advised to by your doctor.

If you stop giving Clamoxyl Duo 400/57 too soon, the infection may not clear completely or your child's symptoms may return.

If you forget to give it

If it is almost time for the next dose, skip the dose you missed and give the next dose when you are meant to.

Otherwise, give the missed dose as soon as you remember, and then go back to giving this medicine as you would normally.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you give too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think your child or anyone else may have taken too much Clamoxyl Duo 400/57.

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

Your child may need urgent medical attention.

While you are giving Clamoxyl Duo 400/57 Suspension

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that your child is taking Clamoxyl Duo 400/57 Suspension.

Tell all the doctors, dentists and pharmacists who are treating your child that he/she is taking Clamoxyl Duo 400/57.

Tell your doctor if your child's symptoms do not improve within a few days, or if they become worse.

If your child develops itching with swelling or skin rash or difficulty breathing while taking Clamoxyl Duo 400/57, do not give him/her any more and tell your doctor immediately.

If your child gets severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after he/she

stopped taking Clamoxyl Duo 400/57.

Diarrhoea may mean that your child has a serious condition affecting your bowel. He/she may need urgent medical care.

Do not give your child any anti-diarrhoeal medicines (eg. Lomotil) without checking with your doctor.

If your child gets a sore, white mouth or tongue while taking or soon after stopping Clamoxyl Duo 400/57, tell your doctor.

This may mean that your child has a fungal infection called thrush. Sometimes, the use of Clamoxyl Duo 400/57 allows fungi to grow and the above symptoms to occur.

Tell your doctor if your child's urine has to be tested for sugar.

Clamoxyl Duo 400/57 may affect the results of these tests.

Tell your doctor if, for any reason, you have not given Clamoxyl Duo 400/57 exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your child's treatment unnecessarily.

Things you must not do

Do not stop giving Clamoxyl Duo 400/57 even if your child feels better after a few days, unless advised to by your doctor.

If you stop giving Clamoxyl Duo 400/57 too soon, the infection may not clear completely or your child's symptoms may return.

Do not use Clamoxyl Duo 400/57 to treat any other conditions unless your doctor tells you to.

Do not give Clamoxyl Duo 400/57 to anyone else, even if they have the same symptoms as your child.

Side effects

Tell your doctor or pharmacist as soon as possible if your child does not feel well while taking Clamoxyl Duo 400/57 Suspension.

Clamoxyl Duo 400/57 helps most people with their infections, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your child may need medical treatment if he/she gets some of the side effects.

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

Do not be alarmed by this list of possible side effects.

Your child may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- * mild diarrhoea
- * indigestion or stomach pain
- * feeling sick (nausea) or vomiting
- * headache, dizziness, tiredness or hot flushes
- * soreness of the mouth or tongue, abnormal taste, "hairy" tongue
- * oral thrush (white, furry sore tongue and mouth)
- * vaginal thrush (sore and itchy vagina, vaginal discharge)

The above list includes the milder side effects of Clamoxyl Duo 400/57 Suspension.

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

- * watery and severe diarrhoea, which may also be bloody
- * severe stomach cramps
- * fever, in combination with one or both of the above
- * signs of anaemia such as looking pale, unusual tiredness or weakness, being short of breath when exercising

- * signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- * bleeding or bruising more easily than normal
- * yellowing of the skin or eyes (jaundice)
- * dark urine or pale stools
- * fits or convulsions

The above side effects are serious and may require medical attention.

Stop giving Clamoxyl Duo 400/57 Suspension and tell your doctor immediately or take your child to Accident and Emergency at the nearest hospital if you notice any of the following:

- * any type of skin rash, itching, blistering or peeling of the skin, hives
- * swelling of the face, lips, mouth or throat which may cause difficulty swallowing or breathing
- * fever, in combination with one or both of the above
- * passing little or no urine

The above side effects are very serious and may require urgent medical attention or even hospitalisation.

Tell your doctor if you notice anything that is making your child feel unwell.

Other side effects not listed above may also occur in some people.

After finishing Clamoxyl Duo 400/57 Suspension

Tell your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with Clamoxyl Duo 400/57:

- * watery and severe diarrhoea, which may also be bloody
- * severe stomach cramps
- * fever, in combination with one or both of the above.

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

Do not give any anti-diarrhoeal medicine (eg. Lomotil) without checking with your doctor.

After giving Clamoxyl Duo 400/57 Suspension

Storage

Keep Clamoxyl Duo 400/57 where children cannot reach it.

Keep Clamoxyl Duo 400/57 in the refrigerator but not in the freezer.

Do not use any mixture left in the bottle after 7 days.

Do not leave Clamoxyl Duo 400/57 in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop giving Clamoxyl Duo 400/57, or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Clamoxyl Duo 400/57 is available as an off-white mixed-fruit flavoured sugar-free suspension.

Each 107 mL bottle contains 60 mL of mixture.

Ingredients

The active ingredients in Clamoxyl Duo 400/57 Suspension are amoxicillin (as amoxicillin trihydrate) and clavulanic acid (as potassium clavulanate).

Each 5 mL of suspension contains:

- * 400 mg of amoxicillin, and
- * 57 mg of clavulanic acid

Clamoxyl Duo 400/57 Suspension also contains the following inactive ingredients:

- * xanthan gum
- * aspartame
- * succinic acid
- * silica - colloidal anhydrous
- * hypromellose
- * silicon dioxide
- * mixed fruit flavour

Clamoxyl Duo 400/57 Suspension does not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

Supplier

Clamoxyl Duo 400/57 Suspension is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration number:

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