

# FLEMING ORAL SUSPENSION®

Amoxicillin/ Potassium clavulanate (228.5mg/ 5mL, 457mg/ 5mL)

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## What is *Fleming oral suspension* used for

*Fleming oral suspension* is used to treat a wide range of infections in the body caused by bacteria. These infections may affect the chest (bronchitis or pneumonia), bladder (cystitis), sinuses (sinusitis), the ears (otitis media), skin, bone and joints, dental infections and uterus infections.

## How *Fleming oral suspension* works

*Fleming oral suspension* is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

## Before you use *Fleming oral suspension*

### -When you must not use it

- If your child is allergic (hypersensitive) to Amoxicillin, Clavulanic acid, Penicillin,

Cephalosporin or any of the other ingredients of *Fleming oral suspension*

- If your child have ever had a severe allergic (hypersensitive) reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck.
- If your child have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.
- If you are not sure, talk to their doctor or pharmacist before giving *Fleming oral suspension*.

### -Before you start to use it

Check with their doctor, pharmacist or nurse before use if your child:

- Have glandular fever
- Are being treated for liver or kidney problems

If you are not sure if any of the above apply to your child, talk to your doctor or pharmacist before giving *Fleming oral suspension*

In some cases, your doctor may investigate the type of bacteria that is causing infection in your child. Depending on the results, your child may be given a different strength of *Fleming oral suspension* or a different medicine.

### -Taking other medications

Please tell your doctor or pharmacist if your child is taking or has recently taken any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.

- If your child is taking allopurinol (used for gout) with *Fleming oral suspension*, it may be more likely that they will have an allergic skin reaction.
- If your child is taking probenecid (used for gout), your doctor may decide to adjust the dose of *Fleming oral suspension*.

- If medicines to help stop blood clots (such as warfarin) are taken with *Fleming oral suspension* then extra blood tests may be needed.
- *Fleming oral suspension* can reduce the efficacy of oral contraceptives

## How to use *Fleming oral suspension*

### -How much to use

Always give this medicine to your child exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This suspension is not usually recommended for children weighing 40kg and over. Ask your doctor or pharmacist for advice.

Children weighing less than 40kg

All doses are worked out depending upon the child's bodyweight in kilograms.

- Your doctor will advice you how much *Fleming oral suspension* you should give to your baby or child. Follow your doctor's instructions
- This medicine is usually given as one dose twice a day

### -When to use it

- Always shake the bottle well before each dose
- Give at the start of a meal or slightly before

### -How long to use it

Keep giving this medicine for the full time of treatment, even if your child begins to feel better after a few days.

If your child do not complete the full course prescribed by your doctor, the infection may not clear completely or your child symptoms may return.

Do not give your child *Fleming oral suspension* for more than 2 weeks. If

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your child still feels unwell, they should go back to see the doctor.

### -If you forget to use it

- Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

### -If you use too much (overdose)

If you give your child too much *Fleming oral suspension*, signs might include an upset stomach (feeling sick being sick or diarrhoea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

### **While you are using it**

#### -Things you must do

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

Keep giving your child *Fleming oral suspension* until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse. If your child get severe diarrhoea tell your doctor or pharmacist immediately.

#### -Things you must not do

This medicine has been prescribed to your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child.

#### -Things to be careful of

*Fleming oral suspension* contains aspartame:

*Fleming oral suspension* contains aspartame (E951) which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'.

### **Side effects**

Tell your doctor or pharmacist as soon as possible if your child do not feel well while taking this medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need urgent medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. Your child may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor or pharmacist if you notice any of the following side effects:

- Oral thrush – white, furry, sore tongue and mouth
- Vaginal thrush – sore and itchy vagina and/or discharge
- Mild or severe diarrhoea with blood, mucus and stomach pain
- Feeling sick - frequent infections such as fever, severe chills, sore throat or mouth ulcers
- Yellowing of the skin (jaundice)
- Fits or seizures
- Unusual bleeding or bruising under the skin
- Dark urine or pale stools
- Shortness of breath, wheezing or difficulty breathing
- Severe blisters and bleeding of the lips, eyes, mouth, nose and genitals

Stop taking *Fleming oral suspension* and contact your doctor immediately if you experience any of the following symptoms:

- Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### **Storage and Disposal of *Fleming oral suspension***

#### -Storage

**Dry powder:** This medicinal product should be stored below 30°C in unopened containers in a dry place. **After reconstitution:** Store in a refrigerator between 2°C to 8°C in the container supplied and use within 7 days.

Shake well before use.

Keep this medicine out of the reach of children.

Don't use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

#### -Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment

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## Product Description

### -What it looks like

*Fleming Oral Suspension* is off-white, free flowing powder which on reconstitution becomes an off-white suspension having a characteristic odour.

### -Ingredients

· Active ingredient(s)

*Fleming Oral Suspension*  
228.5 mg/5ml: Each 5 ml contains 200 mg of amoxicillin and 28.5 mg of clavulanic acid.

*Fleming Oral Suspension*  
457 mg/5ml: Each 5 ml contains 400 mg of amoxicillin and 57 mg of clavulanic acid.

· Inactive ingredient(s)

Silicon Dioxide,  
Hypromellose (E5),  
Aspartame, Colloidal  
Anhydrous Silica,  
Anhydrous Citric Acid,  
Xanthan Gum, Flavour  
Raspberry Dry Powder,  
Flavour Orange Dry  
Powder, Flavour Golden  
Syrup Dry Powder.

### -MAL number

Fleming oral suspension 228.5  
mg/5ml: MAL06061693A

Fleming oral suspension 457  
mg/5ml: MAL09062129A

## Manufacturer

MEDREICH LIMITED,  
Virgonagar, Bangalore - 560 049,  
INDIA

## Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd  
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## Date of revision

-02/12/2020

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