



**WHAT IS IN THIS LEAFLET**

- What BACTOCLAV-DS is and what it is used for?
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**WHAT BACTOCLAV-DS IS AND WHAT IT IS USED FOR?**

Bactoclav-DS 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.

Amoxicillin and potassium clavulanate Dry syrup is used in babies and children to treat the following infections:

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- Bone and joint infections.

**WHAT YOU NEED TO KNOW BEFORE YOU TAKE BACTOCLAV-DS**

**Do not give your child Amoxicillin and potassium clavulanate Dry syrup:**

- if they are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6).
- if they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.
- If they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

**Do not give Amoxicillin and potassium clavulanate Dry syrup to your child if any of the above apply to your child.** If you are not sure, talk to their doctor or pharmacist before giving Amoxicillin and potassium clavulanate Dry syrup.

**Warnings and Precautions**

Check with their doctor, pharmacist or nurse before giving your child Amoxicillin and potassium clavulanate Dry syrup if they:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before giving Amoxicillin and potassium clavulanate Dry syrup.

In some cases, your doctor may investigate the type of bacteria that is causing your child’s infection. Depending on the results, your child may be given a different strength of Amoxicillin and potassium clavulanate Dry syrup or a different medicine.

**Conditions you need to look out for** Amoxicillin and potassium clavulanate Dry syrup can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while your child is taking Amoxicillin and potassium clavulanate Dry syrup, to reduce the risk of any problems.

### **Blood and urine tests**

If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that they are taking Amoxicillin and potassium clavulanate Dry syrup. This is because Amoxicillin and potassium clavulanate Dry syrup can affect the results of these types of tests.

### ***Other medicines and Amoxicillin and potassium clavulanate Dry syrup***

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

If your child is taking allopurinol (used for gout) with Amoxicillin and potassium clavulanate Dry syrup, 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 Amoxicillin and potassium clavulanate Dry syrup

If medicines to help stop blood clots (such as warfarin) are taken with Amoxicillin and potassium clavulanate Dry syrup then extra blood tests may be needed.

Amoxicillin and potassium clavulanate Dry syrup can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Amoxicillin and potassium clavulanate Dry syrup may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

### ***Pregnancy, breast-feeding and fertility***

If your child who is about to take this medicine is pregnant or breast-feeding, thinks they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine.

### ***Driving and using machines***

Amoxicillin and potassium clavulanate Dry syrup can have side effects and the symptoms may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

### ***Amoxicillin and potassium clavulanate Dry syrup contains aspartame:***

- Amoxicillin and potassium clavulanate Dry syrup contains aspartame which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'.

## **3. HOW TO TAKE BACTOCLAV-DS**

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

### **Adults and children weighing 40 kg or over**

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

### **Children weighing less than 40 kg**

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

Your doctor will advise you how much Amoxicillin and potassium clavulanate Dry syrup you should give to your baby or child.

Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component.

The dose of Amoxicillin & clavulanic acid that is selected to treat an individual infection should take into account:

- The expected pathogens and their likely susceptibility to antibacterial agents
- The severity and the site of the infection
- The age, weight and renal function of the patient as shown below.

The use of alternative presentations of Amoxicillin & clavulanic acid (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary.

The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review

### *Elderly*

No dose adjustment is considered necessary.

### *Renal impairment*

Dose adjustments are based on the maximum recommended level of amoxicillin.

No adjustment in dose is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.

#### *Hepatic impairment*

Dose with caution and monitor hepatic function at regular intervals

**DIRECTION FOR USE:** Slowly add boiled and cooled water to the bottle up to the level mark, close the bottle and shake thoroughly. If necessary add water again up to the level mark and shake well.

This medicine is given orally using a graduated syringe

The content of the syringe can be: given directly in the infant or child's mouth,

Or

Given after pouring into a spoon or glass

#### ***Usage of the graduated syringe:***

The amount of medicine per dose is based on the child's weight, as indicated on the syringe which is graduated in kg. In this way, the mark so the plunger directly indicate the dose.

Therefore, as the plunger is pulled up, the graduation read on the plunger corresponds to one dose for a child of the weight indicated.

Two doses should be given daily. One in the morning and one in the evening

This medicine can be give before, during or after meals

#### ***If you give more Amoxicillin and potassium clavulanate Dry syrup than you should***

If you give your child too much Amoxicillin and potassium clavulanate Dry syrup, 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.

#### ***If you forget to give Amoxicillin and potassium clavulanate Dry syrup***

If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose. Do not take a double dose to make up for a forgotten dose.

#### ***If your child stops taking Amoxicillin and potassium clavulanate Dry syrup***

Keep giving your child Amoxicillin and potassium clavulanate Dry syrup 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 medicine, ask your doctor, pharmacist or nurse.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

### **Conditions you need to look out for**

#### **Allergic reactions:**

- skin rash
- inflammation of blood vessels (*Vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- fever, joint pain, swollen glands in the neck, armpit or groin
- swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing
- collapse

Contact a doctor immediately if your child gets any of these symptoms. Stop taking Amoxicillin and potassium clavulanate Dry syrup.

Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever

Contact your doctor as soon as possible for advice if your child gets these symptoms.

Very common side effects

These may affect more than 1 in 10 people diarrhoea (in adults).

### **Common side effects**

These may affect up to 1 in 10 people

- Thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses if affected take Amoxicillin and potassium clavulanate Dry syrup with a meal
- Vomiting diarrhoea (in children).

### **Uncommon side effects**

These may affect up to 1 in 100 people

- Skin rash, itching
- Raised itchy rash (*hives*)
- Indigestion
- Dizziness
- Headache.

Uncommon side effects that may show up in blood tests:

- Increase in some substances (*enzymes*) produced by the liver.

### **Rare side effects**

These may affect up to 1 in 1000 people

- Skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge - *erythema multiforme*)
- If you notice any of these symptoms contact a doctor urgently.

Rare side effects that may show up in blood tests:

- Low number of cells involved in blood clotting
- Low number of white blood cells.

### **Frequency not known**

Frequency cannot be estimated from the available data.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)

Serious skin reactions:

a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface - *toxic epidermal necrolysis*)

- Widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
- A red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*).
- Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

Contact a doctor immediately if your child gets any of these symptoms.

- Inflammation of the liver (*hepatitis*)
- Jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your child's skin and whites of the eyes appear yellow
- Inflammation of tubes in the kidney
- Blood takes longer to clot
- Hyperactivity

- Convulsions (in people taking high doses of Amoxicillin and potassium clavulanate Dry syrup or who have kidney problems)
- Black tongue which looks hairy
- Stained teeth (in children), usually removed by brushing.

Side effects that may show up in blood or urine tests:

- severe reduction in the number of white blood cells
- Low number of red blood cells (*haemolytic anaemia*)
- Crystals in urine.

## **5. HOW TO STORE BACTOCLAV-DS**

Keep this medicine out of the sight and reach of children.

### ***Dry powder***

Store in the original package in order to protect from moisture

Do not store above 25°C. Keep out of the reach of children

Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.

### ***Liquid suspension***

Store in a refrigerator (2°C - 8°C). Do not freeze.

Once made up, the suspension should be used within 7 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### ***What Bactoclav-DS***

*Each 1 ml of reconstituted suspension contains:*

*Amoxicillin Trihydrate BP equivalent to Amoxicillin.....100 mg*

*Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid ...12.5 mg*

### ***What Bactoclav-DS looks like and contents of the pack***

Description

- i) Dry Powder : White to off-white powder
- ii) Reconstituted suspension (0th day & 7th day): White to off-white coloured, flavoured Suspension.

100ml amber color glass bottle is packed in a carton along with pack inert

### **Manufacturer**

**MICRO LABS LIMITED**

27, Race Course road

Bangalore-560001. INDIA

### **Date of Revision**

Mar 2019