**Patient Information Leaflet**

**DAFRACLAV® 200/28**

**Amoxicillin/Clavulanic acid, Powder for paediatric oral suspension**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you have questions or you notice side effects not mentioned in this leaflet, contact your doctor or your healthcare professional. Do not pass this medicine on to others.**

1. **What Dafraclav® is and what it is used for**

Dafraclav® contains amoxicillin and clavulanic acid (ATC code: J01CR02). These are antibiotics, working by killing bacteria that cause infections. Amoxicillin belongs to the group of “penicillins”. Clavulanic acid prevents amoxicillin from being inactivated by enzymes produced by the bacteria.

Dafraclav® 200/28 is used in babies and children to treat following infections: middle ear and sinus infections, respiratory tract infections, urinary tract infections, skin and skin structure infections including dental infections and bone and joint infections.

1. **What you need to know before you give your child Dafraclav® 200/28**

**Do not use if your child**

* Is allergic (hypersensitive) to amoxicillin, clavulanic acid or to any other ingredient of this medicine listed in section 6.
* has ever had a severe allergic (hypersensitive) reaction to any other antibiotic; this can include a skin rash or swelling of the face or neck,
* has ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic

**Warnings and precautions**

***Check with your doctor or pharmacist before giving your child this medicine if they:***

* have glandular fever (infectious mononucleosis),
* are being treted 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 your doctor or pharmacist before giving Dafraclav®.

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

Amoxicllin/Clavulanic acid can make some existing condition 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 Dafraclav® to reduce the risk of any problems.

If your child is having blood tests (such as red blood cell status or liver function tests) or urine tests, let the doctor or nurse know that they are taking Dafraclav®. Dafraclav® can affect the results of these type of tests.

**Other medicines and Dafraclav®**

Please tell your doctor, pharmacist or health care provider if your child is taking or has recently taken any other medicines, including medicines without a prescription.

If your child is taking allopurinol (used for gout) combined with Dafraclav®, it makes an allergic skin reaction more likely;

If your child is taking probenecid (used for gout) , your doctor may decide to adjust the dose of Dafraclav® 200/28;

If medicines to stop blood clots (such as warfarin) are taken with Dafraclav® 200/28 , then extra blood tests may be needed;

Dafraclav® can affect how methotrexate (used to treat cancer or rheumatic diseases) works;

Dafraclav® BD 200/28 may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works;

**Pregnancy and breast-feeding**

If the person who is taking this medicine is pregnant or breast-feeding, you must tell your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Dafraclav® has negligible influence on the ability to drive and use machines.

**Important information about some ingredients of Dafraclav® 200/28**

Dafraclav® 200/28 contains sodium benzoate which may increase jaundice ( yellowing of the skin and eyes) in newborns (up to 4 weeks old).

Dafraclav BD 200/28 mg contains sucrose. If you have been told by your doctor you’re your child has an intolerance to some sugars, contact your doctor before giving this product.

1. **How to use Dafraclav® 200/28**

Always use this medicine exactly as your doctor or health care provider has told you.

**Preparing the suspension** : Free the powder by shaking the bottle. Add water until the half of the bottle and shake well. Wait for 5 minutes for homogeneous disper­sion. Add water until marked level on the bottle (70 ml) and shake well again.

The reconstituted suspension contains 200 mg amoxicillin and 28 mg clavulanic acid per 5 ml.

**Children weighing less than 40 kg**

All doses are calculated depending on the child’s bodyweight in kilograms. Your doctor will advise you how much Dafraclav® 200/28 you should give to your child.

The usual daily dose is 25 mg to 45 mg of amoxicillin per kilogram of bodyweight.

Higher daily dose up to 70 mg of amoxicillin per kilogram of bodyweight.

The daily dose should be given in two equal divided doses, administered 12 hours apart.

Give the dose at the start of a meal. Shake the bottle before giving each dose.

Treatment should not last more than 14 days without an evaluation of the patient.

**Children weighing 40 kg and more**: Use another presentation of Dafraclav® for the treatment.

**Patients with kidney problems or liver problems**

You doctor can prescribe a different dose.

Blood tests may be needed to check liver function.

**Continue to give your child Dafraclav® 200/28**  until the treatment is finished, even if your child feels better. It needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

**If you accidently give more Dafraclav® 200/28 than you should,** signs might include an upset stomach (feeling sick, being sick or diarrhea) or convulsions. Talk to your doctor as soon as possible. Take the medicine carton or bottle to show the doctor.

**If you forget to give Dafraclav® 200/28,** give it as soon as you remember, but wait about 4 hours before giving it again.

If you have any further question on the use of this medicine, ask your doctor or pharmacist.

1. **Possible side effects**

Like all medicines, Dafraclav ® can cause side effects, although not everybody gets them.

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

* **Allergic reactions:** skin rash, red or purple raised spots on the skin, fever, joint pain, swollen glands in the neck, armpit or groin, swelling, sometimes of the face or mouth causing difficulty in breathing, collapse.

If you get any of these symptoms: ***contact a doctor immediately and stop giving Dafraclav® 200/28.***

* **Inflammation of large intestine:** causing watery diarrhea usually with blood and mucus, stomach pain and/or fever.

If you get these symptoms: ***contact your doctor as soon as possible for advice.***

***Other side effects:***

* Very common side effects (more than 1 in 10 people): diarrhea.
* Common side effects (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 Dafraclav® before food); vomiting; diarrhea (in children).
* Uncommon side effects (up to 1 in 100 people): skin rash, itching; raised itchy rash (*hives*); indigestion; dizziness; headache.

Uncommon side effects that may show up in your blood tests: increase in some substances (*enzymes*) produced by the liver.

* Rare side effects (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. Rare side effects that may show up in your blood tests: low number of cells involved in blood clotting; low number of white blood cells.

***Other side effects*** *(in a very small number of people but their exact frequency is unknown*):

* Allergic reactions (see above);
* Inflammation of the large intestine (see above);
* Inflammation of the protective membrane surrounding the brain
* 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)).
* Inflammation of the liver *(hepatitis);*
* Jaundice caused by increases in the blood of bilirubin (a substance produced in the liver) which 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 Dafraclav® 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 your blood or urine tests***:

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or health care provider.

1. **How to store Dafraclav® 200/28**

Keep out of the reach and sight of children.

Store below 30°C, in the original package to protect from moisture.

After reconstitution , the suspension can be used for 7 days when stored in refrigerator (2°C-8°C). Do not put the bottle in the freezer.

Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

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

1. **Contents of the pack and further information**

**What Dafraclav® 200/28 contains**

The active substances are amoxicillin and clavulanic acid. Each 5 ml of suspension contains 200 mg amoxicillin (as amoxicillin trihydrate) and 28 mg clavulanic acid (as potassium clavulanate).

The other ingredients are citric acid, sodium citrate, sodium benzoate, colloidal silica, microcrystalline cellulose, carboxymethylcellulose sodium, xanthan gum, sucrose, raspberry essence.

**What Dafraclav® 200/28 looks like and content of the pack**

Bottle with a white to off-white powder to prepare 70 ml of suspension by adding water.

Box with 1 bottle and a dosing device.

**Dafraclav® 200/28** is a prescription medicine.

**Manufacturer**

Bilim Ilaç San.v.eTc. A.Ş Çerkezköy Organize Sanayi Bölgesi, Karaağaç Mh.5, Sk.N°6 Kapaklı, Tekirdağ, 59510 Turkey.

**Marketing Authorisation Holder**

Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.

**Date of revision of the leaflet**

01/2021