

Package leaflet: Information for the patient.

Dioclav

Co-amoxiclav Tablets (amoxicillin and clavulanic acid)

- Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- This medicine has been prescribed for you (or your child). Do not pass it on to others. It may harm them if used inappropriately.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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What Dioclav is and what it is used for

Dioclav 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.

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

Do not take Dioclav:

- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of Dioclav (listed in section 6) (hypersensitive) reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic. Do not take Dioclav if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Dioclav.

Talk to your doctor or pharmacist before taking this medicine if you:

- are being treated for liver or kidney problems
- are not passing water regularly.
- are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Dioclav.
- in some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of Dioclav or a different medicine. Conditions you need to look out for when taking Dioclav can make some existing conditions worse, or cause new ones. These include: a) a yeast infection of the vagina, mouth or skin (jocks)
- a large intestine. You must look out for certain symptoms while you are taking Dioclav, to reduce the risk of any problems. See "Conditions you need to look out for" in Section 4.
- Blood and urine tests
- If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests, you must tell your doctor that you are taking Dioclav. This is because Dioclav can affect the results of these type of tests.

Using other medicines

- Please tell your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.
- If you are taking aspirin (used for gout) with Dioclav, it may be more likely that you'll have an allergic reaction to aspirin.
 - If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Dioclav.
 - If medicines to help stop blood clots (such as warfarin) are taken with Dioclav then extra blood tests may be needed.
 - Dioclav can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Pregnancy and breast-feeding

- If you are pregnant, you think you might be pregnant or if you are breast-feeding, please tell your doctor or pharmacist for advice before taking any medicine.
- Driving and using machines
- Dioclav can have side effects and the symptoms may make you unfit to drive.
- Always take Dioclav exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- Adults and children weighing 40 kg and over
- Dioclav 625 - the usual dose is 1 tablet three times a day
 - Dioclav 19 - the usual dose is 1 tablet three times a day
- Children weighing less than 40 kg
- Children aged 6 years or less should preferably be treated with Co-amoxiclav oral suspension. Ask your doctor or pharmacist for advice when giving Dioclav tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.
- If you have kidney problems the dose may be changed. A different strength or a different

medicine may be chosen by your doctor.

- If you have liver problems you may have more frequent blood tests to see how your liver is working.

How to take Dioclav

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before. Tablets should be taken on the same time to make them easier to swallow. You must take both pieces of the tablet at the same time.
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Dioclav for more than 2 weeks. If you still feel unwell you should go back to see the doctor.
- Do not take more Dioclav than you should.
- If you have too much Dioclav, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible. Take the medicine carton or bottle to show the doctor.

- If you forget to take a dose, take it as soon as you remember.
- If you should not take the next dose too soon, but wait about 4 hours before taking the next dose. Keep taking Dioclav until the treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back. If you have any questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Dioclav can cause side effects, although not everybody gets them. Conditions you need to look out for

Allergic reactions:

- 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 mouth (angioedema), causing difficulty in breathing

Contact a doctor immediately if you get any of these symptoms. Stop taking Dioclav.

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

Very common side effects

- These may affect more than 1 in 10 people
- diarrhoea (in adults)
 - Common side effects to 1 in 10 people
 - thirst (caused by a yeast infection of the vagina, mouth or skin folds)
 - feeling sick (nausea), especially when taking high doses
 - if affected take Dioclav before food

Uncommon side effects

- These may affect up to 1 in 100 people
- skin rash, itching
 - raised itchy rash (hives)
 - dizziness
 - headache
- Uncommon side effects that may show up in your blood tests:
- increase in some substances (enzymes) produced by the liver.
 - skin rash, with a dark ring around the edge — erythema multiforme

Other side effects

- Inflammation of the large intestine (see above)
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and skin folds (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 (exanthematous pustulosis).

Contact a doctor immediately if you get any of these symptoms.

- inflammation of the liver (hepatitis)
- a darkening of the urine (dark brown or black)
- you may make your skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hypercitraemia (in people taking high doses of Dioclav 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
- reduced blood cells (haemolytic anaemia)
- crystals in urine.

If you get side effects

- Tell your doctor or pharmacist if any of the side effects become severe or troublesome, or if you notice any side effects not listed in this leaflet.
- **How to store Dioclav**
- Store below 30°C. Protected from moisture.
- Do not use Dioclav after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Tablets supplied in pouches should be used within 30 days of opening the pouch.
- Do not use the original pack in order to protect from moisture and light.
- Dioclav tablets should be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

Dioclav tablets 19m: The active substances is 875 mg amoxicillin and 125 mg clavulanic acid (present as potassium clavulanate) in every 1 gm tablet

Dioclav tablets 625mg: The active substances is 500 mg amoxicillin and 125 mg clavulanic acid (present as potassium clavulanate) in every 625mg tablet

Dioclav tablets 19m are: Colloidal silicon dioxide, microcrystalline cellulose, starch glycolate (Type A), isopropyl alcohol, ethylene chloride

Dioclav tablets 625mg are: Colloidal silicon dioxide, microcrystalline cellulose, croscarmellose cross, titanium dioxide, polyethylene glycol-400, isopropyl alcohol

What Dioclav looks like and contents of the pack

Dioclav tablets 19m - It is White to Off white film coated capsule shaped embossed with 603 on one side and scoreline on the other. Film coated tablets

Dioclav tablets 625mg - It is White to Off white oval shaped embossed with 607 on one side and scoreline on the other. Film coated tablets

They are packaged in:

- Dioclav tablets 19m : Strip of 2 tablets and 4 tablets
- Dioclav tablets 625mg : Strip of 2 tablets and 4 tablets

Advisory information

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the reasons for this is that the bacteria are not susceptible to the antibiotic. This means that they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

Dioclav is an antibiotic. It is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right time and at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. Do not stop taking Dioclav unless it has been prescribed specifically for you, and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any questions on the use of this product, ask your doctor or pharmacist or pharmacist. You should take the remainder to a pharmacy, for appropriate disposal.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medication.
- The doctor and the pharmacist are the experts in medicines, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep all medication out of the reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.

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Muscat, Sultanate of Oman.

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