

PACKAGE LEAFLET: INFORMATION FOR THE USER

XICLAV 2X

457 mg / 5 ml powder for oral suspension

AMOXICILLIN, CLAVULANIC ACID

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What XICLAV 2X is and what it is used for
2. Before you take XICLAV 2X
3. How to take use XICLAV 2X
4. Possible side effects
5. How to store XICLAV 2X
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1. WHAT XICLAV 2X IS AND WHAT IT IS USED FOR

XICLAV 2X 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.

XICLAV 2X is used in infants and children, rarely in adults, 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.

2. BEFORE YOU TAKE XICLAV 2X

Do not take XICLAV 2X

- if your child is allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6).
 - if your child has ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.
 - if your child has ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.
- Do not give XICLAV 2X 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 XICLAV 2X.

Take special care with XICLAV 2X

Tell your doctor if your child:

- has infectious mononucleosis (glandular fever)
- is being treated for liver or kidney problems
- is 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 XICLAV 2X.

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 XICLAV 2X or a different medicine.

Conditions you need to look out for

XICLAV 2X 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 XICLAV 2X, to reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

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 the child is taking XICLAV 2X. This is because XICLAV 2X can affect the results of these types of tests.

Taking other medicines

Please tell your doctor if your child is taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking allopurinol (used for gout) with XICLAV 2X, it may be more likely that you will have an allergic skin reaction.

If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of XICLAV 2X.

If medicines to help stop blood clots (such as warfarin) are taken with XICLAV 2X then extra blood tests may be needed.

XICLAV 2X can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

XICLAV 2X can affect how mycophenolate mofetil (a medicine used for the control of the immune system) works.

XICLAV 2X with food and drink

Take the tablet just before meal to prevent possible indigestion and to increase optimal absorption of the medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

XICLAV 2X can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

3. HOW TO TAKE XICLAV 2X

Always take XICLAV 2X exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

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 XICLAV 2X you should give to your baby or child.
- You may be provided with a plastic measuring spoon or plastic measuring cup or dosing syringe. You should use this to give the correct dose to your baby or child.
- Recommended dose – 25 mg/3.6 mg to 45 mg/6.4 mg for each kilogram of body weight a day, given in two divided doses.
- Higher dose – up to 70 mg/10 mg for each kilogram of body weight a day, given in two divided doses.

Patients with kidney and liver problems

- If your child has kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems you may have more frequent blood tests to check how your liver is working.

How to give XICLAV 2X

- Always shake the bottle well before each dose
- Give at the start of a meal or slightly before
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not give your child XICLAV 2X for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.
- Close the bottle after each use.

If you take more XICLAV 2X than you should

If you give your child too much XICLAV 2X, signs might include an upset stomach (feeling sick, being sick or diarrhea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to take XICLAV 2X

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.

If you stop taking XICLAV 2X

Keep giving your child XICLAV 2X 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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 XICLAV 2X.

Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhea 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.

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 XICLAV 2X before food
- vomiting
- diarrhea (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.

Other side effects

Other side effects have occurred 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 (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).

Contact a doctor immediately if you get 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 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 XICLAV 2X or who have kidney problems)
- black tongue which looks hairy

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE XICLAV 2X

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

Do not use this medicine after the expiry date which is stated on the carton (3 years). The expiry date refers to the last day of that month.

Shelf life: 2 years.

Do not store above 25 °C.

Liquid suspension

Store in a refrigerator (2°C – 8°C).

Do not freeze.

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

6. FURTHER INFORMATION

What XICLAV 2X contains

5 ml of oral suspension contains: 400 mg of amoxicillin in the form of amoxycillin trihydrate and 57 mg of clavulanic acid in the form of potassium salt.

XICLAV 2X powder for oral suspension contains the following excipients: citric acid, anhydrous milled, milled sodium citrate anhydrous, microcrystalline cellulose and sodium carboxymethylcellulose dried, xanthan gum, colloidal silicon dioxide, silicon dioxide, cherry flavor, lemon flavor, dried saccharin sodium, mannitol.

What XICLAV 2X looks like and contents of the pack

XICLAV 2X powder for oral suspension is a white to yellowish white crystalline powder.

XICLAV 2X prepared suspension is white to yellow homogeneous suspension.

XICLAV 2X powder for oral suspension is packed in glass bottles for the preparation of 70 ml of suspension. Original package includes a dosing syringe of 5 ml for the correct dosage of medicine.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Bosnalijek d.d.

Jukićeva 53, Sarajevo, Bosna i Hercegovina

Manufacturer of the medicinal product

Bosnalijek dd (In cooperation with Lek dd, Ljubljana, Verovškova 57, Slovenia)

Jukićeva 53, Sarajevo, Bosnia and Herzegovina

Advice/medical education

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 commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. 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.

When your doctor prescribes a course of 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 dose, 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. You should not take an antibiotic 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. .

Instructions for reconstitution

Shake bottle to loosen powder. Add 59 ml of water (as indicated below) divided into two parts (first 2/3 and then up to the mark on the bottle) and shake until you get a suspension. Shake the bottle well before each dose.