

Patient Information Leaflet

TICASSE® 200/28

Amoxicillin + Clavulanic Acid
POWDER FOR PEDIATRIC ORAL SUSPENSION

Read all of this leaflet carefully before you start taking this medicine because it contains important information.

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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.

1. What is Ticasse® 200/28 and what it is used for

Ticasse® 200/28 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.

Ticasse® 200/28 is used in the treatment of the following infections:

- respiratory tract infections (including middle ear and sinus infections),
- skin and skin structure infections (including dental infections),
- urinary tract infections.

2. What you need to know before you give your child Ticasse® 200/28

Do not give your child Ticasse® 200/28 if it

- is allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of Ticasse® 200/28 (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.

Take special care with Ticasse® 200/28 if your child

- has glandular fever (infectious mononucleosis),
- has 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 Ticasse® 200/28.

Special warnings and precautions for use

- inflammation of the large intestine has been reported in association with all antibiotics including amoxicillin/clavulanic acid; this possibility should be taken into consideration if your child has diarrhea,
- if allergic reactions occur during therapy, treatment should be discontinued immediately.

Other medicines and Ticasse® 200/28

Please tell your doctor or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription and herbal medicines:

- probenecid (used for gout) can make an adjustment of your dose of Ticasse® 200/28 necessary;
- allopurinol (used for gout) combined with Ticasse® 200/28 makes an allergic skin reaction more likely;
- Ticasse® 200/28 should not be used in conjunction with disulfiram;
- warfarin and other medicines to help stop blood clots taken with Ticasse® 200/28 may make extra blood tests needed;
- methotrexate (used to treat cancer or rheumatic diseases) can be affected by Ticasse® 200/28;
- Ticasse® 200/28 may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works;
- blood and urine tests: if you are 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 you are taking Ticasse® 200/28.

Pregnancy, breast-feeding and fertility

If your child is or could be pregnant or if it is breast-feeding, please tell your doctor or pharmacist.

Driving and using machines

Ticasse® 200/28 has negligible influence on the ability to drive and use machines.

3. How to give Ticasse® 200/28

Always give it exactly as your doctor or pharmacist has told you.

Directions for mixing oral suspension:

1. add water until the half of the bottle and shake well.
2. wait for 5 minutes for homogeneous dispersion.
3. add water until marked level on the bottle and shake well again.

The reconstituted suspension contains 200 mg amoxicillin and 28 mg clavulanic acid per 5 ml and is active for 7 days when stored in refrigerator. Do not put the bottle in the freezer.

Shake the bottle well before each use.

Posology:

Children weighing less than 40 kg (in adults and children weighing more than 40 kg, adult dosing schedule is applied):

- All doses are calculated according to the child's bodyweight in kilograms. Your doctor will advise you how much Ticasse® 200/28 you should give to your baby or child.
 - Recommended dose: 25 mg to 45 mg amoxicillin for each kilogram of body weight a day, given in two equal portions, administered every 12 hours.
 - A measuring spoon is provided: you should use this to give the correct dose to your baby or child.
 - Ticasse® 200/28 has to be taken at the start of a meal.
 - The treatment should not last more than 14 days without evaluation of the patient.
 - **Let your child keep taking Ticasse® 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 accidentally give more Ticasse® 200/28 than you should**, 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 give Ticasse® 200/28**, give it as soon as you remember, but wait about 4 hours before giving it again.
- If you have any further questions about the use of this medicine, ask your doctor or pharmacist.**

4. Possible side effects

Like all medicines, Ticasse® 200/28 can cause side effects, although not everybody gets them.

At high dose levels the incidence of side effects is higher.

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 taking Ticasse® 200/28.**
- **Inflammation of large intestine:** causing watery diarrhoea 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): diarrhoea.
- 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 Ticasse® 200/28 before food); vomiting; diarrhoea (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 (*exanthematous pustulosis*); inflammation of the liver (*hepatitis*); jaundice; inflammation of tubes in the kidney; blood takes longer to clot; hyperactivity; convulsions (in people taking high doses of Ticasse® 200/28 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.

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

5. **How to store Ticasse® 200/28 powder for oral suspension:** Store below 25°C, in the original package, in a dry place in order to protect from moisture. Keep out of reach and sight of children. Do not use this medicine if the expiry date printed on the pack (Exp.) has passed. After reconstitution with water: store maximum 7 days in the refrigerator. Do not freeze.

6. Other information

What Ticasse® 200/28 contains per 5 ml after reconstitution: Amoxicillin Trihydrate equivalent to 200 mg Amoxicillin and Potassium Clavulanate equivalent to 28 mg Clavulanic Acid. Other ingredients: Citric acid, Sodium citrate, Sodium benzoate, Colloidal silica, Microcrystalline cellulose, Carboxymethylcellulose, Xanthan gum, Sucrose, Raspberry essence.

Ticasse® 200/28 is presented in a cardboard containing 1 bottle, with a cream coloured powder to give 70 ml suspension after reconstitution with water. Supplied with a measure device.

Ticasse® 200/28 is a prescription only medicine.

Name of Manufacturer: Bilim Pharmaceuticals. Çerkezköy Plant, 59500 Çerkezköy/Tekirdağ - Turkey.

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Date of Revision of This Text: May 2016.