

Patient Information Leaflet

TICASSE

Amoxicillin/clavulanic acid 500 mg/62,5 mg, powder for oral suspension in dose-sachet (ratio (8/1))

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 Ticasse is and what it is used for

Ticasse contains amoxicillin and clavulanic acid (ATC J01CR02). These antibiotics work by killing bacteria that cause infections. 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.

Ticasse is used in adults 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.

2. What you need to know before you give your child Ticasse

Do not use Ticasse if your child

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

Do not use Ticasse if any of the above apply. If you are not sure, talk to your doctor or pharmacist before giving your child this medicine.

Warnings and precautions

Check with your doctor or pharmacist before giving Ticasse 500mg/62.5mg, powder for oral suspension in dose-sachet to your child , if she/he:

- has glandular fever
- is being treated for liver or kidney problems
- is not passing water regularly.

In some cases, your doctor may investigate the type of bacteria that is causing the infection.

Depending on the results, the doctor may prescribe a different strength of Ticasse or a different medicine.

Conditions you need to look out for

Ticasse 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 you are taking Ticasse, 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 he/she is taking Ticasse. This is because Ticasse can affect the results of these types of tests.

Other medicines and Ticasse

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

If the patient is taking allopurinol (used for gout) with Ticasse, it may be more likely that you will have an allergic skin reaction.

If the patient is taking probenecid (used for gout), your doctor may decide to adjust the dose of Ticasse.

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

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

Ticasse can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy and breast-feeding

If the person taking this medicine is pregnant or breastfeeding, please tell your doctor or pharmacist. Ask your doctor or pharmacist for advice before taking any medication.

Driving and using machines

Ticasse can have side effects and the symptoms may make you unfit to drive.

Important information about some ingredients of Ticasse

Ticasse 500mg/62.5mg powder for oral suspension in dose-sachet contains 17,5 mg aspartame in each sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take Ticasse 500 mg/62.5mg powder for oral suspension in dose-sachet

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

Adults and children weighing 40 kg or over

The 500mg/62.5 mg sachets are usually not recommended for adults and children weighing 40 kg and over. Ask your doctor or pharmacist for advice.

Use in children and adolescents ≤40 kg

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

- Recommended dose: 40 mg/5 mg to 80 mg/10 mg for each kilogram of body weight a day, given in three divided doses.
- Your doctor will advise you how much Ticasse you should give to your baby or child.

Method of administration

- Just before use of Ticasse, open the sachet and mix its contents in half a glass of water.



1. Tear the top of the sachet and pour the powder in a glass.



2. Add some water.



3. Stir well for a few seconds. Drink immediately.

- Give the mixture to your child at the start of a meal or a little before.
- Distribute the doses evenly throughout the day; they must be spaced at least by 4 hours. Do not take 2 doses in 1 hour.
- Do not give Ticasse for more than 2 weeks. If the symptoms persist, consult again doctor.

Patients with kidney problems and liver problems

In the event of kidney problems, an adjustment of the dosage may be necessary. The doctor may prescribe a different strength or a different medication.

If you have liver problems, more frequent blood tests may be needed to check the how the liver is working.

If you give more Ticasse than you should

Signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions when administering of an excessive amount of Ticasse. Talk to your doctor as soon as possible. Take the medicine pack to show the doctor.

If you forget to give Ticasse

If you miss a dose, give it as soon as you remember it. Then wait about 4 hours before giving the next dose. Do not give a double dose to make up for a forgotten dose.

If you stop using Ticasse

You should continue to give Ticasse to your child until the end of treatment, even if he/she you feel better. All the doses are important to help fight the infection. If some bacteria survive they can cause the infection to come back.

Your doctor will instruct you how long you should take this medicine.

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

4. Possible side effects

Like all medicines, Ticasse 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 the patients gets any of these symptoms. Stop Ticasse administration.

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 the patient 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
- 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 the patient 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 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 Ticasse 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.

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.

5. How to store Ticasse

Keep out of the reach and sight of children.

Store below 30°C

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 your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and further information

What Ticasse 500mg/62.5mg powder for oral suspension in dose-sachet contains

The active substances are amoxicillin (500 mg as amoxicillin trihydrate) and clavulanic acid (62.5 mg as potassium clavulanate).

The other ingredients are Colloidal silica, hydrated, Crospovidone, Microcrystalline cellulose, Colloidal silica, anhydrous, Magnesium stearate, Aspartame, Strawberry flavour.

What Ticasse 500mg/62.5mg powder for oral suspension in dose-sachet looks like and content of the pack

Sachet containing a white to off-white granular powder.

Box with 15 dose-sachets.

Ticasse is a prescription medicine.

Manufacturer

Medicef Pharma, Plot No. – 28, 29 & 48 EPIP, Phase-I, Jharmajri, Baddi, (HP).Distt: Solan, Himachal Pradesh, INDIA

Marketing Authorisation Holder

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

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