Ticasse®

amoxicillin & clavulanic acid

The winning combination of
amoxicillin, clavulanic acid and the Dafra quality

INDICATIONS	SEVERITY	TABLETS	SUSPENSION (From 3 months)
Upper respiratory tract infections	Less severe / moderate	625 mg 3 x / day	12,5 mg/kg 2 x / day
	severe	1000 mg 2 x / day	22,5 mg/kg 2 x / day
Lower respiratory tract infections	Less severe / moderate	625 mg 3 x / day	12,5 mg/kg 2 x / day
	severe	1000 mg 2 x / day	22,5 mg/kg 2 x / day
Soft tissue and skin infections	Less severe / moderate	625 mg 3 x / day	12,5 mg/kg 2 x / day
	severe	1000 mg 2 x / day	22,5 mg/kg 2 x / day
Urinary tract infections	Less severe / moderate	625 mg 3 x / day	12,5 mg/kg 2 x / day
	severe	1000 mg 2 x / day	22,5 mg/kg 2 x / day

Renal impairment: dosage adjustment if the glomerular filtration rate <30 ml / min.

DAFRA PHARMA INTERNATIONAL

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Dafra PHARMA

Setting the Standard

www.dafrapharma.com

Ticasse®

amoxicillin & clavulanic acid

EUROPEAN GMP

The winning combination of amoxicillin, clavulanic acid and the Dafra quality

Suitable dosage:
1 pack = 1 basic treatment of seven days

First-choice antibiotic for ENT, respiratory tract and skin infections

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PRESENTATION

- **TICASSE® 1000 mg tablet**, box of 14 Amoxicillin 875 mg + Clavulanic acid 125 mg.
- **TICASSE® 625 mg tablet**, box of 15 Amoxicillin 500 mg + Clavulanic acid 125 mg.
- **TICASSE® 457 mg, powder** for 70 ml of oral suspension.
  Amoxicillin 400 mg + Clavulanic acid 57 mg per 5-ml measuring spoon.
- **TICASSE® 228 mg, powder** for 70 ml of oral suspension.
  Amoxicillin 200 mg + Clavulanic acid 28.5 mg per 5-ml measuring spoon.

THERAPEUTIC PROPERTIES

TICASSE® is an antibiotic of the B-lactamine family.

PHARMACODYNAMICS

Clavulanic acid irreversibly inhibits most of the B-lactamases produced by Gram-positive and Gram-negative bacteria. **TICASSE®** has demonstrated activity against a large number of resistant bacteria via secretion of B-lactamases (penicillinases), regardless of whether this resistance is acquired or natural.

PHARMACOKINETICS

Amoxicillin and clavulanic acid are very well absorbed at the gastrointestinal level. After administration of **TICASSE®**, excellent diffusion of the amoxicillin in most of the tissues and fluids is seen, except for the brain and cerebrospinal fluid.

INDICATIONS

TICASSE® is indicated for infections due to sensitive Gram (+) and Gram (-) bacteria.
(In particular, pathogens which synthesize ß-lactamase and which, for this reason, are resistant to amoxicillin alone).

- **ENT infections**
  Tonsillitis, pharyngitis, laryngitis, otitismedia, sinusitis, essentially due to Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis and Streptococcus pyogenes.
- **Lower respiratory tract infections**
  Acute bronchitis with bacterial superinfection and acute exacerbations of chronic bronchitis, bacterial pneumonia, essentially caused by Streptococcus pneumoniae, Haemophilus influenzae and Moraxella catarrhalis.
- **Urinary infections**
  Acute and chronic pyelonephritis, cystitis, urethritis and others due to Escherichia coli.
- **Gastrointestinal infections**
  Typhoid fever, paratyphoid, shigellosis (bacillary dysentery).
- **Venereal diseases**
  Gonorrhoea (specific urethritis).
- **Infections of the skin and soft tissues**
  Essentially caused by Staphylococcus aureus and Streptococcus pyogenes.

The official recommendations for appropriate use of antibiotics should be followed, namely the recommendations regarding use, to avoid an increase in antibiotic resistance.

ADVERSE EFFECTS

The combination of amoxicillin/clavulanic acid is generally well tolerated. In clinical trials, most of the adverse effects reported are mild and transient. Less than 3% of patients discontinued their treatment due to adverse effects. Diarrhoea (9%), nausea (3%), skin rash and urticaria(3%) and vomiting (1%) are the adverse effects most often reported. At high doses, the frequency

of these adverse effects and headaches have been frequently reported. The following adverse effects were noted with this class of ampicillin antibiotics: diarrhoea, nausea, vomiting, indigestion, gastritis, stomatitis, glossitis, black hairy tongue, microcutaneouscandidiasis, enterocolitisand haemorrhage, pseudomembranous colitis, skin rash, pruritus, urticaria, angioedema, reaction similar to serum sickness and, rarely, exfoliativedermatitis. These reactions can be controlled by the administration of antihistamines and, if necessary, corticosteroids.

CONTRAINDICATIONS

TICASSE® is contraindicated in patients with a past history of penicillin allergy. It is also contraindicated in patients with a past history of cholestaticjaundice or hepatic dysfunction resulting from the use of amoxicillin/clavulanic acid.

DRUG INTERACTIONS

Probenecidinhibits renal tubular secretion of amoxicillin and increases its plasma concentrations. **TICASSE®** should not be used simultaneously with probenecid. Simultaneous use of ampicillin and allopurinol increases the incidence of skin rash. It is not known if this is due to the allopurinol or the hyperuricemia. **TICASSE®** may not be used together with disulfiram.

INTERACTIONS WITH DIAGNOSTIC TESTS

Amoxicillin passes into the urine at elevated concentrations and can cause tests used to reveal the presence of glucose in urine to yield false-positive results. During a test for the presence of glucose in the urine, it is recommended to use tests based on the enzymatic glucose-oxidase method. The administration of amoxicillin in pregnant women causes an increase in the levels of conjugated estriol, estriolglucuronide, conjugated estroneand estradiolin the serum. Pregnancy category B: Although animal testing has not revealed a teratogenic potential of amoxicillin/clavulanic acid, controlled studies have not yet been conducted in humans. **TICASSE®** may be used during pregnancy only if absolutely necessary.

DOSAGE

Tablets, 625 mg

The usual dose for adults and children weighing 40 kg or more is 1 tablet of **TICASSE®** 625 mg every 12 hours. In the event of serious infections and airway infections, it is recommended to take 1 tablet of **TICASSE®** 625 mg every 8 hours. In patients with kidney disease, no dose adjustment is necessary unless the renal failure is very severe.

Tablets, 1000 mg

The usual dose for adults and children aged 12 years and over: for the treatment of severe infections and infections of the respiratory tract, the dose is 1 tablet of **TICASSE®** 1000 mg every 12 hours.

TICASSE® 1000 mg should not be used in cases of renal failure when the glomerular filtration rate is less than 30 ml/min. **TICASSE®** should be taken before or during meals. This improves absorption of the clavulanic acid.

5 ml suspension 200/28 mg or 400/57 mg

Paediatric patients aged 12 weeks (3 months) or over.

Infections	Dosing regimen
Otitis media, sinusitis, infections of the respiratory tract and more severe infections	45 mg/kg/day, the daily dose is divided into two equal doses taken 12 hours apart.
Less severe infections	25 mg/kg/day, the daily dose is divided into two equal doses taken 12 hours apart.

USE DURING BREASTFEEDING

Antibiotics of the ampicillin class pass into breast milk. **TICASSE®** should be used with caution in breastfeeding women.

EFFECTS ON ABILITY TO DRIVE VEHICLES AND USE MACHINERY

TICASSE® has no pharmacodynamicaction which could impair the ability to drive or use machinery.

STORAGE

Do not use without seeking medical advice.

Store below 25 °C, in the original package, protected from humidity. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

After reconstitution, it can be stored for 7 days in the refrigerator. Shake well before use.

For the complete SMPC, please visit www.dafrapharma.com