Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Rapiclav 625mg tablet

2. Qualitative and quantitative composition

Each film coated tablet contains:

Amoxicillin Trihydrate BP

Equivalent to Amoxicillin 500 mg

Clavulanate Potassium

Equivalent to Clavulanic Acid 125 mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Film-coated tablet

White to off-white oval shaped, biconvex film coated tablets

4. Clinical particulars

4.1. Therapeutic Indications

The combination of amoxicillin and clavulanic acid is indicated in the following infections:

URTI including recurring tonsillitis, otitis media and Sinusitis.

LRTI, including acute exacerbation of chronic bronchitis, pneumonia & bronchopneumonia. Uncomplicated & complicated, simple & recurrent

UTI such as cystitis, urethritis and pyelonephritis. Skin and soft tissue infections. Gynecological infections. Post-operative infections. Intra-abdominal infections.

4.2. Posology and Method of Administration Adults

The usual adult oral dosage of amoxicillin and clavulanate potassium is one 375 mg film coated tablet every 8 hours or one 625 mg film coated tablet every

12 hours. For more severe infection and infections of the respiratory tract, the usual adult oral dose is one 625 mg film coated tablet every 8 hours.

Children

Children weighing more than 40kg or more may receive usual oral dose of amoxicillin and clavulanate potassium. The dosage of amoxicillin and clavulanate potassium in neonates and infants younger than 12 weeks of age is 30mg/kg of amoxicillin daily given in divided doses every 12 hours. For the treatment of otitis media, sinusitis, lower respiratory tract infections and more severe infections in pediatric patients 12 weeks of age and older, the usual dosage of amoxicillin and clavulanate potassium is 40mg/kg of amoxicillin daily in divided doses every 8 hours. The 375mg tablet should be used in children who weigh less than 40kg.

Patients with impaired renal function

Generally, reduction in doses is not required unless the impairment is severe. Patients with a glomerular filtration rate of 10 to 30 ml/min should receive 625mg or 375mg every 24 hours depending on the severity of the infection. Patients with less than 10ml/min glomerular filtration rate should receive 625mg or 375mg every 24 hours, depending on the severity of the infection.

Patients on hemodialysis

Hemodialysis patients should receive 625 or 375 mg every 24 hours depending on the severity of the infection. They should receive an additional dose both during and at the end of dialysis.

Patients with hepatic impairment

Hepatically impaired patients should be dosed with caution and hepatic function monitored at regular intervals.

4.3. Contra-indications

Amoxicillin and clavulanic acid is contraindicated in patients who are hypersensitive to any penicillin. It should be used with caution in patients with evidence of hepatic dysfunction.

4.4 Special Warnings and Special Precautions for Use

Warnings and precautions

Prior to initiation of therapy with amoxicillin and clavulanic acid, careful inquiry should be made concerning previous hypersensitivity reactions, to penicillins, cephalosporin's, or other drugs.

Renal, hepatic and hematological functions should be evaluated periodically during prolonged therapy with co amoxiclav.
Ingestion of alcohol should be avoided during and for several days after treatment with the combination.

Pregnancy and lactation

There are no adequate or controlled studies using amoxicillin and clavulanic acid in pregnant women, and the drug should be used during pregnancy only when clearly needed.

Amoxicillin is excreted in breast milk; there is no data on the excretion of clavulanic acid in human milk.

Trace quantities of clavulanate can be detected in breast milk. With the exception of the risk of sensitization associated with this excretion, there are no known detrimental effects for the breast-fed infant.

4.5. Interaction with other Medicinal Products and other forms of Interaction Drug interactions

Concomitant use of probenecid and amoxicillin and clavulanic acid may result in the increased and prolonged levels of amoxicillin but not of clavulanic acid. Amoxicillin + clavulanic acid combination may reduce the efficacy of oral contraceptive. The concurrent administration of allopurinol and amoxicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving amoxicillin. It is not known whether this potentiation of rashes is due to allopurinol or the hyperuricemia presenting these patients. There are no data with amoxicillin /clavulanic acid and allopurinol administered concurrently.

Drug food interactions

Amoxicillin/clavulanic acid may be taken without regard to meals. Dosing in the fasting or fed state has minimal effect on the pharmacokinetics of amoxicillin but absorption of the clavulanate potassium when taken with food is greater relative to the fasted state Thus to minimize the potential for

gastrointestinal in tolerance, amoxicillin/clavulanic acid should be taken at the start of the meal.

Adverse reactions

The combination is well tolerated. The majority of side effects observed in clinical trials were of a mild and transient nature. Gastrointestinal reactions seen include gastritis, stomatitis, glossitis, black 'hairy' tongue, enterocolitis, mucocutaneous candidiasis and antibiotic-associated colitis (including pseudomembranous colitis and hemorrhagic colitis). Hypersensitivity reactions like skin rashes, pruritus and urticaria, serum-sickness like syndrome, erythema multiforme, rare cases of Stevens-Johnson syndrome, hypersensitivity vasculitis and less frequently bullous exfoliative dermatitis and toxic epidermal necrolysis have been reported.
Serious and occasional fatal hypersensitivity (anaphylactic) reactions and angioneurotic oedema can occur with oral penicillin, Interstitial nephritis may occur rarely. Hematopoietic and lymphatic reactions like hemolytic anemia, reversible thrombocytopenia, purpura, eosinophilia, reversible leucopenia and agranulocytosis have been reported during therapy with penicillins. Prolongation of bleeding time and prothrombin time have also been reported less frequently. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly.

Central Nervous System effects: CNS effects have been seen rarely. These include reversible hyperactivity, dizziness, headache and convulsions. Convulsions may occur with impaired renal function or in those receiving high doses.

4.7. Effects on Ability to Drive and Use Machines

Not known.

4.8 Undesirable effects

Side effects are uncommon and mainly of a mild and transitory nature.

Gastrointestinal reactions:
Diarrhea, indigestion, nausea, vomiting, and mucocutaneous candidiasis have been reported. Antibiotic-associated colitis (including pseudomembranous colitis and hemorrhagic colitis) has been reported rarely. Nausea, although uncommon, is more often associated with higher oral dosages. If gastrointestinal side effects occur with oral therapy, they may be reduced by taking Augmentin at the start of meals. Superficial tooth

discoloration has been reported rarely, mostly with the suspension. It can usually be removed by brushing.

Renal and urinary tract disorders:

Crystalluria has been reported very rarely (see Section 4.9 Overdose).

Genito-urinary effects:

Vaginal itching, soreness and discharge may occur.

Hepatic effects:

Moderate and asymptomatic rises in AST and/or ALT and alkaline phosphatases have been reported occasionally. Hepatitis and cholestatic jaundice have been reported rarely. These hepatic reactions have been reported more commonly with Augmentin than with other penicillins.

After Augmentin hepatic reactions have been reported more frequently in males and elderly patients, particularly those over 65 years. The risk increases with duration of treatment longer than 14 days.
Signs and symptoms usually occur during or shortly after treatment but in some cases may not occur until several weeks after treatment has ended. Hepatic reactions are usually reversible but they may be severe and, very rarely, deaths have been reported.

Hypersensitivity reactions:

Urticarial and erythematous skin rashes sometimes occur. Rarely erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative dermatitis, acute generalized exanthematous pustulosis (AGEP), serum sickness-like syndrome and hypersensitivity vasculitis have been reported. Treatment should be discontinued if one of these disorders occurs. In common with other -lactam antibiotics angioedema and anaphylaxis have been reported. Interstitial nephritis can occur rarely.

Hematological effects:

As with other -lactams transient leucopenia (including neutropenia and agranulocytosis), thrombocytopenia and hemolytic anemia have been reported rarely. Prolongation of bleeding time and prothrombin time has also been reported rarely (see 4.5).

CNS effects:

CNS effects have been seen very rarely. These include reversible hyperactivity, dizziness, headache and convulsions. Convulsions may occur with impaired renal function or in those receiving high doses.

Clinical laboratory test findings:

Oral administration of tis formulation will result in high urine concentrations of amoxicillin. High urine concentrations of ampicillin may result in false-positive reactions when testing for the presence of glucose in urine using, Benedict's Solution, or Fehling's Solution. Since this effect may also occur with amoxicillin, it is recommended that glucose tests based on enzymatic glucose oxidase reactions be used.

Following administration of ampicillin to pregnant women, a transient decrease in plasma concentration of total conjugated estriol, estriol-glucuronide, conjugated estrone and estradiol has been noted. This effect may also occur with amoxicillin.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9. Overdose

Most patients have been asymptomatic following overdosage or have experienced primary gastrointestinal symptoms including stomach and abdominal pain, vomiting and diarrhea. Rash, hypersensitivity, or drowsiness have also been observed in a small number of patients.

In case of the overdose, discontinue amoxicillin/clavulanic acid, treat symptomatically, and institute supportive measures are required. If the overdosage is very recent and there is no contraindication, an attempt at emesis or other means of removal of drug from the stomach may be performed. A study pf pediatric patients suggested that overdosages of less than 250mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying
Interstitial nephritis resulting in oliguric renal failure has been reported in small number of patients after overdosage with amoxicillin. Renal impairment appears to be reversible with cessation of drug administration. High blood level may occur more readily in patients with impaired renal function because of decreased renal clearance of both amoxicillin and clavulanate. Both amoxicillin and clavulanate removed from the circulation by hemodialysis.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological activity of the product:

The combination of amoxicillin and clavulanic acid usually is bactericidal in action. Concurrent administration of clavulanic acid does not alter the mechanism of action of amoxicillin. However, because clavulanic acid has a high affinity for and binds to certain b- lactamases that generally inactivate amoxicillin by hydrolyzing its b-lactam ring, concurrent administration of the drug with amoxicillin results in a synergistic bactericidal effect which expands the spectrum of activity of amoxicillin against many strains of b-lactamase producing bacteria that are resistant to amoxicillin alone. Clavulanic acid acts generally as an irreversible, competitive inhibitor of b-lactamases.

5.1. Pharmacodynamic Properties

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5.2. Pharmacokinetic Properties

Crossover studies using fixed combination of amoxicillin and clavulanate, amoxicillin alone and clavulanate alone indicate that concomitant administration of clavulanic acid doses not affect the pharmacokinetics of amoxicillin.

Amoxicillin trihydrate and clavulanic acid are both generally stable in the presence of acidic gastric secretions and are well absorbed following oral administration. Peak serum concentrations of amoxicillin and clavulanic acid are generally attained within 1-2.5 hours following oral administration of a single dose of Co-amoxiclav in fasting adults. Following administration of combination, amoxicillin and clavulanic acid are both distributed into lungs, pleural fluid and peritoneal fluid. Low concentration of each drug is attained in sputum and saliva. Only minimal concentrations of amoxicillin and clavulanic acid are attained in the CSF following oral administration of co amoxiclav in patients with uninflamed meninges; higher concentrations may be attained when meninges are inflamed. Amoxicillin is 17-20% bound to serum proteins.

Clavulanic acid is reportedly 22-30% bound to serum proteins at a concentration of 1- 100ug/mL. Amoxicillin and clavulanic acid readily cross

the placenta. Amoxicillin and clavulanic acid are distributed into milk in low concentrations. Serum concentrations of both the drugs decline in a biphasic manner and half-lives of the drug are similar. Following oral administration of co-amoxiclav in adults with normal renal function, amoxicillin has an elimination half-life of 1-1.3 hours and clavulanic acid has a distribution half-life of 0.28 hours and an elimination half-life of 0.78-1.2 hours. Following oral administration of a single dose in adults with normal renal function, approximately 50-73% and 25-45% of amoxicillin and clavulanic acid are both removed by hemodialysis. Clavulanic acid is excreted in urine principally by glomerular filtration.

5.3. Preclinical Safety

Data

Not applicable.

6. Pharmaceutical particulars

6.1. List of Excipient(s)

Colloidal Silicon Dioxide BP

Croscarmellose Sodium BP,

Microcrystalline Cellulose BP

Magnesium Stearate BP

Hydroxy Propyl Methyl Cellulose BP

Dibutyl Phthalate BP

Purified Talc BP

Titanium Dioxide BP

Isopropyl Alcohol BP

Methylene Chloride USNF.

6.2. Incompatibilities

None known

6.3 Shelf Life

24 months

6.4. Special Precautions for

Storage

Store below 30°C, in a dry place.

6.5. Nature and Contents of Container

Strip of 3 tablets, 7 such strips packed in a printed show box along with a leaflet.

6.6. Instruction for Use/Handling and Disposal

No data of relevance which is additional to that already included in other sections of the SPC.

7. Marketing Authorization Holder

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E-Mail: ipca@ipca.com

8. Marketing Authorization Number

CTD 14806

9. Date of first authorization/renewal of the authorization

23 Jan 2026

10. Date of revision of the text

23 Jan 2026