SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Rapiclav- 156.25 Suspension {Co- Amoxiclav Oral Suspension BP (125+31.5) mg/5ml}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of reconstituted Suspension contains:

Amoxicillin Trihydrate BP equivalent to Amoxicillin 125.0 mg

Diluted Potassium Clavulanate BP equivalent to Clavulanic acid....31.5mg.

Full list of excipients, section 6.1

3. PHARMACEUTICAL FORM

White to off white powder. Suspension

4. CLINICAL PARTICULARS

4.1 INDICATIONS

To reduce the development of drug-resistant bacteria and maintain the effectiveness of amoxicillin and clavulanate potassium and other antibacterial drugs, amoxicillin and clavulanate potassium suspension should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Amoxicillin and clavulanate potassium combination is indicated in the treatment of infections caused by susceptible isolates of the designated bacteria in the conditions listed below.

Lower respiratory tract infections (e.g. acute exacerbation of chronic bronchitis, community acquired pneumonia): Caused by β-lactamase-producing isolates of *H. influenzae and M. catarrhalis.*

Acute bacterial otitis media: Caused by β-lactamase-producing isolates of *H. influenzae and M. catarrhalis.*

Acute bacterial sinusitis: Caused by β-lactamase-producing isolates of *H. influenzae and M. catarrhalis.*

Skin and skin structure infections (in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis): Caused by β-lactamase-producing isolates of *S. aureus, E. coli and Klebsiella spp.*

Urinary tract infections (e.g. cystitis, pyelonephritis): Caused by β-lactamase-producing isolates of *E. coli*, *Klebsiella* spp. and *Enterobacter* spp.

Bone and joint infections, in particular osteomyelitis

Limitations of use

When susceptibility test results show susceptibility to amoxicillin, indicating no beta-lactamase production, amoxicillin and clavulanate potassium combination should not be used.

4.2 DOSAGE AND ADMINISTRATION

Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component.

The dose of Rapiclav Suspension that is selected to treat an individual infection should take into account:

The expected pathogens and their likely susceptibility to antibacterial agents

- The severity and the site of the infection
- The age, weight and renal function of the patient as shown below.

For adults and children ≥ 40 kg, this formulation provides a total daily dose of 1500 mg amoxicillin/375 mg clavulanic acid, when administered as recommended belowFor children < 40 kg, this formulation of Rapiclav suspension provides a maximum daily dose of 2400 mg amoxicillin/600 mg clavulanic acid, when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of amoxicillin/clavulanate potassium is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid.
The duration of therapy should be determined by the response of the patient. Some infections (*e.g.* osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review.

Adults and children ≥ 40 kg

One 500 mg/125 mg dose taken three times a day.

Children < 40 kg

20 mg/5 mg/kg/day to 60 mg/15 mg/kg/day given in three divided doses.

No clinical data are available on doses of amoxicillin and clavulanic acid 4:1 formulations higher than 40 mg/10 mg/kg per day in children under 2 years.
Elderly No dose adjustment is considered necessary.

Renal impairment

Dose adjustments are based on the maximum recommended level of amoxicillin.
No adjustment in dose is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.

Adults and children ≥ 40 kg

CrCl: 10-30 ml/min	500 mg/125 mg twice daily
CrCl < 10 ml /min	500 mg/125 mg once daily
Haemodialysis	500 mg/125 mg every 24 hours, plus 500 mg/125 mg during dialysis, to be repeated at the end of dialysis (as serum concentrations of both amoxicillin and clavulanic acid are decreased)

Children < 40 kg

CrCl: 10-30 ml/min	15 mg/3.75 mg/kg twice daily (maximum 500 mg/125 mg twice daily)
CrCl < 10 ml /min	15 mg/3.75 mg/kg as a single daily dose (maximum 500 mg/125 mg)
Haemodialysis	15 mg/3.75 mg/kg per day once daily. Prior to haemodialysis 15 mg/3.75 mg/kg. In order to restore circulating drug levels, 15 mg/3.75 mg per kg should be administered after haemodialysis.

Hepatic impairment

Dose with caution and monitor hepatic function at regular intervals.

Method of administration

Rapiclav suspension is for oral use.
Amoxicillin and clavulanate potassium suspension may be taken without regard to meals; however, absorption of clavulanate potassium is enhanced when amoxicillin and clavulanate potassium suspension is administered at the start of a meal. To minimize the potential for gastrointestinal intolerance, amoxicillin and clavulanate potassium suspension should be taken at the start of a meal.
Shake to loosen powder, add water as directed, invert and shake.
Shake the bottle before each dose.

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substances, to any of the penicillins or to any of the excipients.

- History of a severe immediate hypersensitivity reaction (*e.g.* anaphylaxis) to another beta-lactam agent (*e.g.* a cephalosporin, carbapenem or monobactam).
- History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid.

4.4 WARNINGS & PRECAUTIONS

Hypersensitivity reactions: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta-lactam antibacterials, including amoxicillin and clavulanate potassium. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. Before initiating therapy with amoxicillin and clavulanate potassium combination, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, other beta lactam agents or other allergens. If an allergic reaction occurs, amoxicillin and clavulanate potassium combination should be discontinued and the appropriate therapy instituted. Serious anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids and airway management, including intubation, should also be administered as indicated.

***Clostridium difficile* Associated Diarrhea (CDAD):** *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including amoxicillin and clavulanate potassium combination, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile.*

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation

should be instituted as clinically indicated. Anti-peristaltic medicinal products are contra-indicated in this situation.

Hepatic dysfunction: Hepatic dysfunction, including hepatitis and cholestatic jaundice has been associated with the use of amoxicillin and clavulanate potassium. It has been reported more commonly in the elderly, in males, or in patients on prolonged treatment. The histologic findings on liver biopsy have consisted of predominantly cholestatic, hepatocellular, or mixed cholestatic-hepatocellular changes. The onset of signs/symptoms of hepatic dysfunction may occur during or several weeks after therapy have been discontinued. Hepatic toxicity is usually reversible, however deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects.

Skin rash in patients with mononucleosis: A high percentage of patients with mononucleosis who receive amoxicillin develop an erythematous skin rash. Thus, amoxicillin and clavulanate potassium should not be administered to patients with mononucleosis.

Potential for microbial overgrowth: The possibility of superinfections with fungal or bacterial pathogens should be considered during therapy. If superinfection occurs, amoxicillin and clavulanate potassium should be discontinued and appropriate therapy instituted.

Development of drug-resistant bacteria: Prescribing amoxicillin and clavulanate potassium in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient, and increases the risk of the development of drug-resistant bacteria.

Others: Amoxicillin and clavulanate potassium combination is not suitable for use when there is a high risk that the presumptive pathogens have reduced susceptibility or resistance to beta-lactam agents that is not mediated by beta-lactamases susceptible to inhibition by clavulanic acid. Amoxicillin and clavulanate potassium combination should not be used to treat penicillin-resistant *S. pneumoniae*. Prolonged use may occasionally result in overgrowth of non-susceptible organisms. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

The occurrence at the treatment initiation of a feverish generalised erythema associated with pustula may be a symptom of acute generalised exanthemous pustulosis (AGEP). This reaction requires amoxicillin and clavulanate potassium combination discontinuation and contra-indicates any subsequent administration of amoxicillin.

In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria. In patients with bladder catheters, a regular check of patency should be maintained.

In patients with renal impairment, the dose should be adjusted according to the degree of impairment.

Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function is advisable during prolonged therapy.

Prolongation of prothrombin time has been reported rarely in patients receiving amoxicillin and clavulanate potassium combination. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

Rapiclav Suspension contains aspartame, which is a source of phenylalanine. This medicine should be used with caution in patients with phenylketonuria

4.5 Interaction with other medicinal products and other forms of interaction

Oral anticoagulants: Oral anticoagulants and penicillin antibiotics have been widely used in practice without reports of interaction. However, in the literature there are cases of increased international normalised ratio in patients maintained acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary.

Methotrexate: Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.

Probenecid: Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin, but does not delay renal excretion of clavulanic acid. Concomitant use of probenecid may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid.

Mycophenolate mofetil: In patients receiving mycophenolate mofetil, reduction in pre-dose concentration of the active metabolite mycophenolic acid of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in pre-dose level may not accurately represent changes in overall MPA exposure. Therefore, a change in the dose of mycophenolate mofetil should not normally be necessary in the absence of clinical evidence of graft dysfunction. However, close clinical Hepatic function should be monitored at regular intervals in patients with hepatic impairment. Amoxicillin and clavulanate potassium should be used with caution in patients with evidence of hepatic impairment. monitoring should be performed during the combination and shortly after antibiotic treatment

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Allopurinol: The concurrent administration of allopurinol and amoxicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving amoxicillin alone. It is not known whether this potentiation of amoxicillin rashes is due to allopurinol or the hyperuricemia present in these patients.

Oral contraceptives: Amoxicillin and clavulanate potassium may affect intestinal flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives.

Disulfiram: Amoxicillin and clavulanate potassium combination should not be used in patients receiving disulfiram.

4.6 Fertility, pregnancy and lactation

Usage in pregnancy and lactation

Limited data on the use of amoxicillin and clavulanate potassium during pregnancy in humans do not indicate an increased risk of congenital malformations. In a single study in women with preterm, premature rupture of the foetal membrane it was reported that prophylactic treatment with amoxicillin and clavulanate potassium may be associated with an increased risk of necrotising enterocolitis in neonates. Use

should be avoided during pregnancy, unless considered essential by the physician.

Both substances are excreted into breast milk (nothing is known of the effects of clavulanic acid on the breast fed infant). Consequently, diarrhoea and fungus infection of the mucous membranes are possible in the breast-fed infant, so that breast-feeding might have to be discontinued. The possibility of sensitisation should be taken into account. Amoxicillin and clavulanate potassium should only be used during breast-feeding after benefit/risk assessment by the physician in charge.

Usage in paediatrics

Efficacy and safety of amoxicillin and clavulanate potassium combination has been established even in neonates in suspension formulation. Paediatric patients weighing 40 kg or more should be dosed according to the adult recommendations. Because of incompletely developed renal function in neonates and young infants, the elimination of amoxicillin may be delayed; clavulanate elimination is unaltered in this age group. Dosing of amoxicillin and clavulanate potassium should be modified in pediatric patients aged < 12 weeks (< 3 months).

Usage in geriatrics

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

4.7 Effects on ability to drive and use machines –

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines.

4.8 Undesirable Effects .

The most commonly reported adverse drug reactions (ADRs) are diarrhoea, nausea and vomiting.

The following terminologies have been used in order to classify the occurrence of undesirable effects.

Very common (≥1/10)

Common (≥1/100 to <1/10)

Uncommon (≥1/1,000 to <1/100)

Rare (≥1/10,000 to <1/1,000)

Very rare (<1/10,000)

Not known (cannot be estimated from the available data)

Blood and lymphatic system disorders – *Rare:* Reversible leucopenia (including neutropenia), thrombocytopenia; *Not known:* Reversible agranulocytosis, anaemia including haemolytic anaemia, thrombocytopenic purpura, thrombocytosis, eosinophilia, prolongation of bleeding time and prothrombin time.

Gastrointestinal disorders –*Common:* Diarrhoea, nausea (Nausea is more often associated with higher oral doses. If gastrointestinal reactions are evident, they may be reduced by taking amoxicillin/clavulanic acid at the start of a meal)/loose stools, vomiting; *Uncommon:* Indigestion, abdominal discomfort, flatulence; *Not known:* Antibiotic-associated colitis (including pseudomembranous colitis, enterocolitis and hemorrhagic colitis), black hairy tongue, gastritis, stomatitis, glossitis. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment. Tooth discoloration (brown, yellow, or gray staining) has been reported. Most reports occurred in pediatric patients. Discoloration was reduced or eliminated with brushing or dental cleaning in most cases.

Hepatobiliary disorders - *Uncommon*: Rises in AST and/or ALT (A moderate rise in AST and/or ALT had been noted in patients treated with beta-lactam class antibiotics, but the significance of these findings is unknown); *Not known:* Hepatic dysfunction including Hepatitis (These events have been noted with other penicillins and cephalosporins), cholestatic jaundice, rise in serum bilirubin, and/or alkaline phosphatase, cholangitis.

Immune system disorders - *Not known*: Angioneurotic oedema, anaphylaxis, serum sickness-like reactions (urticaria or skin rash accompanied by arthritis, arthralgia, myalgia, and frequently fever), hypersensitivity vasculitis.

Infections and infestations – *Common:* Mucocutaneous candidiasis, vaginitis; *Not known:* Overgrowth of non-susceptible organisms.

Nervous system disorders – *Uncommon*: Dizziness, headache; *Not known*: Aseptic meningitis, agitation, anxiety, behavioral changes, confusion, convulsions, dizziness,

insomnia, and reversible hyperactivity.

Renal and urinary disorders - *Not known*: Interstitial nephritis, hematuria, crystalluria

Skin and subcutaneous tissue disorders (If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued) – *Uncommon*: Skin rash, pruritus, urticaria, diaper area rashes; *Rare*: Erythema multiforme; *Not known*: Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis (including toxic epidermal necrolysis), acute generalised exanthemous pustulosis (AGEP), Drug reaction with eosinophilia and systemic symptoms (DRESS).

4.9 OVERDOSAGE

Following overdosage, patients have experienced primarily gastrointestinal symptoms including stomach and abdominal pain, vomiting, and diarrhea. Disturbance of the fluid and electrolyte balances may be evident. Rash, hyperactivity, or drowsiness have also been observed in a small number of patients.

Interstitial nephritis resulting in oliguric renal failure has been reported in a small number of patients after overdosage with amoxicillin and clavulanate potassium combination.

Crystalluria, in some cases leading to renal failure, has also been reported after amoxicillin and clavulanate potassium overdosage in adult and pediatric patients. In case of overdosage, adequate fluid intake and diuresis should be maintained to reduce the risk of amoxicillin and clavulanate potassium crystalluria.

Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of both amoxicillin and clavulanate potassium.

Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Amoxicillin has been reported to precipitate in bladder catheters, predominantly after intravenous administration of large doses. A regular check of patency should be maintained.

In case of overdosage, discontinue the drug, treat symptomatically, and institute supportive measures as required.

Gastrointestinal symptoms may be treated symptomatically, with attention to the water/electrolyte balance.

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.

Amoxicillin and clavulanate potassium may be removed from the circulation by hemodialysis.

5. CLINICAL PHARMACOLOGY

5.1 Pharmacodynamic properties

Pharmacodynamics

Pharmacotherapeutic group: Amoxicillin and clavulanate potassium is an oral antibacterial combination consisting of the semisynthetic antibiotic amoxicillin and the β-lactamase inhibitor, clavulanate potassium (the potassium salt of clavulanic acid).

ATC code : J01CR02

5.2 Mechanism of Action

Pharmacotherapeutic group: Combinations of penicillins, incl. beta-lactamase inhibitors.

Amoxicillin is a semisynthetic penicillin (beta-lactam antibiotic) that inhibits one or more enzymes (often referred to as penicillin-binding proteins, PBPs) in the biosynthetic pathway of bacterial peptidoglycan, which is an integral structural component of the bacterial cell wall. Inhibition of peptidoglycan synthesis leads to weakening of the cell wall, which is usually followed by cell lysis and death.

Amoxicillin is susceptible to degradation by beta-lactamases produced by resistant bacteria and therefore the spectrum of activity of amoxicillin alone does not include organisms which produce these enzymes.

Clavulanic acid is a beta-lactam structurally related to penicillins. It inactivates some beta-lactamase enzymes thereby preventing inactivation of amoxicillin. Clavulanic acid alone does not exert a clinically useful antibacterial effect.

The formulation of amoxicillin and clavulanic acid protects amoxicillin from degradation by β-lactamase enzymes and effectively extends the antibiotic spectrum of amoxicillin to include many bacteria normally resistant to amoxicillin.

Commonly susceptible species

Aerobic Gram-positive micro-organisms

Enterococcus faecalis
Gardnerella vaginalis
*Staphylococcus aureus (*methicillin-susceptible*)*[£]
Coagulase-negative *staphylococci* (methicillin-susceptible)
Streptococcus agalactiae
Streptococcus pneumonia [1]
Streptococcus pyogenes and other beta-hemolytic streptococci
Streptococcus viridans group

Aerobic Gram-negative micro-organisms

Capnocytophaga spp.
Eikenella corrodens
Haemophilus influenza [2]
Moraxella catarrhalis
Pasteurella multocida

Anaerobic micro-organisms
Bacteroides fragilis
Fusobacterium nucleatum
Prevotella spp

Species for which acquired resistance may be a problem

Aerobic Gram-positive micro-organisms

Enterococcus faecium[$]

Aerobic Gram-negative micro-organisms

Escherichia coli Klebsiella
oxytoca Klebsiella
pneumoniae Proteus
mirabilis Proteus vulgaris

Inherently resistant organisms

Aerobic Gram-negative micro-organisms

Acinetobacter sp. *Citrobacter*
freundii Enterobacter sp.
Legionella pneumophila
Morganella morganii
Providencia spp.
Pseudomonas sp.

Serratia sp.

Stenotrophomonas maltophilia

Other micro-organisms
Chlamydophila pneumoniae
Chlamydophila psittaci
Coxiella burnetti
Mycoplasma pneumonia

[$] Natural intermediate susceptibility in the absence of acquired mechanism of resistance.

£ All methicillin-resistant staphylococci are resistant to amoxicillin/clavulanic acid.

[1] *Streptococcus pneumoniae* that is fully susceptible to penicillin may be treated with this presentation of amoxicillin/clavulanic acid.

[2] Strains with decreased susceptibility have been reported in some countries in the EU with a frequency higher than 10%.

5.3 Pharmacokinetics

Both amoxicillin and clavulanic acid are rapidly and well absorbed by the oral route of administration. Following oral administration, amoxicillin and clavulanic acid are approximately 70% bioavailable. About 25% of total plasma clavulanic acid and 18% of total plasma amoxicillin is bound to protein.

Amoxicillin is partly excreted in the urine as the inactive penicilloic acid in quantities equivalent to up to 10 to 25% of the initial dose. Clavulanic acid is extensively metabolized in man and eliminated in urine and faeces and as carbon dioxide in expired air.

The major route of elimination for amoxicillin is via the kidney, whereas for clavulanic acid it is by both renal and non-renal mechanisms. Approximately 50% to 70% of amoxicillin and approximately 25% to 40% of clavulanic acid are excreted unchanged in the urine during the first 6 hours after administration of single amoxicillin and clavulanate potassium 250 mg/125 mg or -500 mg /125mg mg. The half-life of amoxicillin after the oral administration of amoxicillin and clavulanate potassium is 1.3 hours and that of clavulanic acid is 1.0 hour.

6. PHARMACEUTICAL PARTICULARS

6.1 Full List of excipients:

- Silicon Dioxide USP-NF
- Colloidal Silicon Dioxide (Aerosil-200) USP-NF
- Xanthan Gum USP-NF
- Hypromellose (Methocel E 5) Ph.Eur.
- Aspartame BP
- Succinic Acid USP-NF
- Raspberry Flavor IHT
- Orange Flavor IHT

- Golden Syrup IHT

6.2 Incompatibilities

None

6.3 Shelf life

Dry powder: 2 years

Shelf life after reconstitution : 7 days

6.4 Special precautions for storage

Store below 30° C in a dry place

Reconstituted suspensions should be stored at 2°C - 8°C (but not frozen) for up to 7 days

KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

25 mm white opaque, polypropylene screw cap with tamper evident ring & XL SR 531 liner.

Bottle (Glass) 30ml/25mm Clear, Transparent, Round

Bottle of 30 ml and 60 ml

6.6 Special precautions for disposal

Shake bottle to loosen powder. Add volume of water (as indicated below). Close, invert and shake well.

Alternatively, shake the bottle to loosen powder then fill the bottle with water to just below the line on the label. Close, invertand shake well, then top up with water exactly to the line. Close, invert and again shake well.

Strength	Volume of water to be added atreconstitution (ml)	Final volume of reconstituted oral suspension(ml)
125 mg/31.25 mg/5 ml	28	30

Shake the bottle well before each dose.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ipca Laboratories Ltd.
Regd. Office: 48, Kandivli Industrial Estate,
Mumbai 400 067,
India.

8. Marketing authorisation number(s)

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9. Date of first authorisation/renewal of the authorisation

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10. Date of revision of the text

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