1.5 Product Information

1.5.1 Prescribing information (Summary of products characteristics)

1. Name of the Medicinal Product
Amoxicillin and Clavulanate Potassium for oral Suspension USP

1.1 Product Name
INFICLAV 228.5

1.2 Strength
200 mg + 28.5 mg / 5ml

1.3 Pharmaceutical Dosage Form
Dry Powder for oral Suspension

2. Quality and Quantitative Composition

2.1 Qualitative Declaration
Amoxicillin Trihydrate USP + Clavulanate Potassium USP

2.2 Quantitative Declaration
200 mg + 28.5 mg / 5ml

3. Pharmaceutical Form
White to off-white coloured, flavoured, free flowing granules give white coloured homogeneous suspension after reconstitution.

4. Clinical Particulars

4.1 Therapeutic indications
It is indicated for short term treatment of bacterial infections at the following sites: Upper Respiratory Tract Infections (including ENT) in particular sinusitis, otitis media, recurrent tonsillitis. (caused by Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis and Streptococcus pyogenes)
Lower Respiratory Tract Infections in particular acute exacerbations of chronic bronchitis (especially if considered severe), bronchopneumonia (caused by Streptococcus pneumoniae, Haemophilus influenzae and Moraxella catarrhalis)
Genito-urinary Tract and Abdominal Infections in particular cystitis (especially when recurrent or complicated - excluding prostatitis), septic abortion, pelvic or puerperal sepsis and intraabdominal sepsis. (caused by Enterobacteriaceae, Staphylococcus saprophyticus, Enterococcus species)
Skin and Soft Tissue Infections in particular cellulitis, animal bites and severe dental abscess with spreading cellulitis. (caused by Staphylococcus aureus, Streptococcus pyogenes and Bacteroides species)

4.2 Posology and method of administration

Usual dosages for the treatment of infection

Adults and children over 12 years of age:	This formulation is not applicable to this age group
Children under 12 years of age:	The usual recommended daily dosage is 25 mg/kg/day in divided doses every eight hours. The table below presents guidance for it.
Under 1 year	25 mg/kg/day , for example a 7.5 kg child would require 2 ml three times a day
1- 6 years (10-18 kg)	5ml three times a day.
Over 6 years (18-40 kg)	10 ml three times a day
In more serious infections the dosage may be increased up to 50 mg/kg/day in divided doses every eight hours.	

Dosage in renal impairment: Mild impairment (creatinine clearance>30 ml/min): no change in dosage.

Moderate to severe impairment (creatinine clearance <30 ml/min): A reduction in dosage should be made in proportion to the recommendation for adults.

Dosage in hepatic impairment: Dose with caution; monitor hepatic function at regular intervals. There are, as yet, insufficient data on which to base a dosage recommendation.

Administration: To minimise potential gastrointestinal intolerance, administer at the start of a meal. The absorption of Sharpclav 228.5 is optimised when taken at the start of a meal. Duration of therapy should be appropriate to the indication and should not exceed 14 days without review.

Reconstitution of powders:-To reconstitute suspension, add boiled & cooled water up to the mark on the bottle. Shake vigorously and adjust the volume up to mark. Reconstituted suspension should be stored in a refrigerator & used within 7 days.

4.3 Contraindications

History of penicillin allergy; history of amoxicillin and Clavulanate associated cholestatic jaundice or liver disease.

4.4 Special warning and precautions for use

Changes in liver function tests have been observed in some patients receiving Sharpclav 228.5. The clinical significance of these changes is uncertain but Sharpclav 228.5 should be used with caution in patients with evidence of hepatic dysfunction.

Cholestatic jaundice, which may be severe, but is usually reversible, has been reported rarely. Signs and symptoms may not become apparent for several weeks after treatment has ceased.

In patients with renal impairment, dosage should be adjusted according to the degree of impairment In patients with reduced urine output, crystalluria has been observed very rarely, redominantly 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.
Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy.

Erythematous rashes have been associated with glandular fever in patients receiving amoxicillin. Prolonged use may also occasionally result in overgrowth of non- susceptible organisms. Redamox Suspension contains Aspartame so care should be taken in phenylketonuria.

4.5 Interaction with other medicinal products and other forms of interactions

Allopurinol: Additive potential for amoxicillin rash. Aminoglycosides: May be synergistic against selected organisms.

Fusidic acid: May decrease the therapeutic effect of penicillins; administer the penicillin at least 2 hours before fusidic acid.

Methotrexate: Penicillins may increase the exposure to methotrexate during concurrent therapy; monitor. Oral contraceptives: Anecdotal reports suggesting decreased contraceptive efficacy with penicillins have been refused by more rigorous scientific and clinical data.

Probenecid: May increase levels of penicillins (amoxicillin); concomitant use not recommended. Warfarin: Effects of warfarin may be increased.

4.6 Pregnancy and lactation

Amoxicilin & Potassium Clavulanate Suspension should be administered to pregnant women and neonatal infants only when clearly needed.

4.7 Effects on ability to drive and use machine

None

4.8 Undesirable effects

CNS: Agitation; anxiety; behavioral changes; confusion; convulsions; dizziness; fatigue; headache; insomnia; reversible hyperactivity.
Dermatologic: Skin rashes, urticaria erythema multiforme; maculopapular to exfoliative dermatitis; pruritus; vesicular eruptions.
ENT: Abnormal taste sensation; black hairy tongue; glossitis; itchy eyes; laryngeal edema; laryngospasm; sore or dry mouth or tongue; stomatitis.
GI: Diarrhea/loose stools; nausea; vomiting; abdominal pain or cramps; anorexia; bloody diarrhea; enterocolitis; epigastric distress; flatulence; gastritis; pseudomembranous colitis; rectal bleeding.
Genitourinary: Vaginitis; interstitial nephritis (eg, oliguria, proteinuria, hematuria, hyaline casts, pyuria); nephropathy.
Hematologic: Agranulocytosis; anemia; increased basophils; bone marrow depression; eosinophilia;granulocytopenia; hemolytic anemia; increased monocytes; increased or decreased lymphocyte count; leukopenia; neutropenia; increased platelets; prolonged bleeding and prothrombin time; reduced hemoglobin or hematocrit; thrombocytopenia; thrombocytopenic

purpura.

Hepatic: Cholestatic jaundice; transient hepatitis.

Metabolic: Reduced albumin; elevated serum alkaline phosphatase and hypernatremia;reduced serum potassium; reduced total proteins and uric acid.

Miscellaneous: Hyperthermia; superinfection.

4.9 Overdose

Nausea, vomiting and diarrhoea may occur with overdosing. Treatment is symptomatic and supportive. Amoxicillin and clavulanic acid may be removed from the circulation by haemodialysis.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Amoxicillin is a bactericidal semisynthetic aminobenzyl penicillin (p-hydroxy ampicillin). It inhibits cross-linking of structures of the cell wall by binding to transpeptidases. The resulting instability leads by way of lysis to death of the cell. Clavulanic acid is a natural product of Streptomyces clavuligerus and its structure resembles that of the penicillin nucleus. It possesses only slight antibacterial activity itself but it irreversibly inhibits chromosome-coded beta-lactamases of Richmond classes II, IV and VI and plasmid- coded beta-lactamases of Richmond classes III and V.

By concomitant administration of clavulanic acid and amoxicillin the latter is protected from degradation by beta-lactamases. Consequently, the combination of amoxicillin and clavulanic acid is active against numerous amoxicillin-resistant bacterial strains.

5.2 Pharmacokinetic Properties

The pharmacokinetics of amoxicillin and clavulanic acid are closely allied and neither are adversely affected by the presence of food in the stomach, and are stable in the presence of gastric acid. The oral bioavailability of amoxicillin and potassium clavulante is approximately 90% and 75% respectively. Peak serum levels of both occur about 1-2 hour after oral administration.

Clavulanic acid has about the same plasma elimination half-life (1 hour) as that of amoxicillin (1,3 hours). It is eliminated primarily unchanged through the renal route. Approximately 50-78% of amoxicillin and 25-40% of clavulanic acid are excreted unchanged in urine within the first 6 hrs. after administration.

5.3 Preclinical safety Data

No relevant information

6. Pharmaceutical Particulars

6.1 List of Excipients

1. Sodium Citrate
2. Microcrystalline cellulose with Carmellose sodium
3. Aspartame
4. Orange flavor Powder
5. Microcrystalline cellulose
6. Xanthan Gum

6.2 Incompatibilities

None

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store in cool dry place below 30°C. Protect from light.

Re-constituted Suspension mixture should store in a refrigerator between 2°C to 8°C & used within 7 days.

6.5 Nature and contents of container

100 ml ring marked Amber Glass Bottle

6.6 Special precautions for disposal and other handling

Not applicable

7. Manufacturer

Sakar Healthcare Limited,
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Changodar, Dist : Ahmedabad, Gujarat,
India, Pin code-382213

8. Date of publication or revision

Will be included after registration