G-moxil CLAV

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Amoxycillin and Clavulanate for Tablets, Syrup.

COMPOSITION

G-MOXIL CLAV 625 mg Tablets
Each film-coated tablet contains
Amoxycillin trihydrate IP
equivalent to Amoxycillin . . . . . 500 mg
Clavulanic acid..... 125 mg
(Present as clavulanate potassium IP)

G-MOXIL CV 375 mg Tablets
Each film-coated tablet contains
Amoxycillin trihydrate IP
equivalent to Amoxycillin . . . . . 250 mg
Clavulanic acid..... 125 mg
(Present as clavulanate potassium IP)

G-MOXIL CLAV 228.5 mg Syrup
Each 5 ml (on reconstitution) contains
Amoxycillin trihydrate IP
equivalent to Amoxycillin . . . .200 mg
Clavulanate Potassium IP
equivalent to Clavulanic acid ..... 28.5 mg

G-MOXIL CV DS 457 mg Syrup
Each 5 ml (on reconstitution) contains
Amoxycillin trihydrate IP
equivalent to Amoxycillin . . . .400 mg
Clavulanate Potassium IP
equivalent to Clavulanic acid ..... 57 mg

INDICATIONS

G-MOXIL CLAV is indicated for short-term treatment of bacterial infections at the following sites:

i. Upper Respiratory Tract Infections(including ENT) e.g.recurrent tonsillitis, sinusitis, otitis media
ii. Lower Respiratory Tract Infections e.g.acute exacerbation of chronic bronchitis, lobar and bronchopneumonia
iii. Genito-urinary Tract Infections e.g. cystitis, urethritis, pyelonephritis
iv. Skin and Soft Tissue Infections e.g. boils, abscesses, cellulitis, wound infections, animal bites
v. Bone and Joint Infections e.g. osteomyelitis
vi. Other infections e.g. intra-abdominal sepsis, septic abortion, puerperal sepsis
vii. Dental infections: eg dentoalveolar abscess, severe dental abscess with spreading cellulitis

DOSAGE AND ADMINISTRATION

Oral Administration

To minimize potential gastrointestinal intolerance, administer at the start of a meal. The absorption of G-MOXIL CLAV is optimized when taken at the start of a meal. Treatment should not be extended beyond 14 days without review.

G-MOXIL CLAV Tablets

Adults and Children over 12 years

Usual dosages for the treatment of infection.

Mild to Moderate Infections	One 625 mg tablet twice a day.
Severe Infections	625 mg tablets Four times a day.

Dentoalveolar abscess one G-MOXIL CLAV 625 mg tablet twice a day for five days.

Renal Impairment

Adults

Patients with impaired renal function do not generally require a reduction in dose unless the impairment is severe. Severely impaired patients with a glomerular filtration rate of <30 mL/min. should not receive the 1g tablet.

Mild impairment (Creatinine clearance > 30 mL/min)	No change in dosage.
Moderate impairment (Creatinine clearance 10-30 mL/min)	One 625 mg tablet twice a day. 1 g tablet should not be administered.
Severe impairment (Creatinine clearance <10 mL/min)	Not more than one 625 mg tablet every 24 hours.

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

Hepatic Impairment

Dose with caution; monitor hepatic function at regular intervals.

G-MOXIL CLAV 625mg tablet is not recommended in children of 12 years and under.

Tablets should be swallowed whole without chewing. If required, tablets may be broken in half and swallowed without chewing.

Patients aged 2 years and older:

Mild to Moderate infections(upper respiratory tract infections e.g. recurrent tonsillitis, lower respiratory tract infections and skin and soft tissue infections)	25/3.6 mg/kg/day	b.i.d
Severe Infections (upper respiratory tract infections e.g., Otitis media, sinusitis, lower respiratory tract infections e.g. bronchopneumonia and urinary tract infections)	45/6.4 mg/kg/day	b.i.d

There is insufficient experience with **G-MOXIL CLAV 228.5 mg DT** to make dosage recommendations for children under 2 months old.

Infants with immature kidney function

For infants with immature renal function **G-MOXIL CLAV 228.5 mg DT** is not recommended.

Renal impairment

For children with GFR of > 30 mL/min no adjustment in dosage is required. For children with a GFR of < 30 mL/min **G-MOXIL CLAV 228.5 mg DT** is not recommended.

Hepatic impairment

Dose with caution; monitor hepatic function at regular intervals. There is, as yet, insufficient evidence on which to base a dosage administration.

Disperse the **G-MOXIL CLAV 228.5 mg DT** in 10 ml of water before administration.

G-MOXIL CLAV Syrup

Usual dosages for the treatment of infection.

Mild to Moderate infections (upper respiratory tract infections e.g. recurrent tonsillitis, lower respiratory tract infections and skin and soft tissue infections)	25/3.6 mg/kg/day
Severe Infections (upper respiratory tract infections e.g., Otitis media, sinusitis, lower respiratory tract infections e.g. bronchopneumonia and urinary tract infections)	45/6.4 mg/kg/day

The table below gives guidance for children.

Children over 2 years:

25/3.6 mg/kg/day	2-6 years (13-21 kg)	5.0 ml**G-MOXIL CLAV 228.5 mg Syrup**b.i.d
	7-12 years (22-40 kg)	10.0 ml**G-MOXIL CLAV 228.5 mg Syrup**b.i.d
45/6.4 mg/kg/day	2-6 years (13-21 kg)	10.0 ml**G-MOXIL CLAV 228.5 mg Syrup**b.i.d
	7-12 years (22-40 kg)	20.0 ml**G-MOXIL CLAV 228.5 mg Syrup**b.i.d

Children under 2 years should be dosed according to body weight.

	G-MOXIL CLAV 228.5 mg Syrup	
Weight (kg)	25/3.6 mg/kg/day (ml/b.i.d)	45/6.4 mg/kg/day (ml/b.i.d)
2	0.5	1.0
3	0.8	1.5
4	1.1	2.0
5	1.4	2.5
6	1.6	3.0
7	1.9	3.4
8	2.2	3.9
9	2.5	4.4
10	2.7	4.9
11	3.0	5.4
12	3.3	5.9
13	3.6	6.4
14	3.8	6.9
15	4.1	7.4

There is insufficient experience with **G-MOXIL CLAV 228.5 mg Syrup** to make dosage recommendations for children under 2 months old.

Infants with immature kidney function
For infants with immature renal function **G-MOXIL CLAV 228.5 mg Syrup** is not recommended.

Renal impairment
For children with GFR of > 30 mL/min no adjustment in dosage is required. For children with a GFR of < 30 mL/min **G-MOXIL CLAV 228.5 mg Syrup** is not recommended.

Hepatic impairment
Dose with caution; monitor hepatic function at regular intervals. There is, as yet, insufficient evidence on which to base a dosage administration.

Instructions for use/handling

Direction for preparing the suspension
At the time of dispensing, the dry powder should be reconstituted to form an oral suspension. First shake the bottle to loosen powder. Twist and open the vial of sterile water given with the pack. Slowly add sterile water into the bottle up to black arrow mark on the label. Put the cap, and shake the bottle vigorously. *Adjust the volume upto the black arrow mark by adding more sterile water, if necessary* and shake again. Store the reconstituted suspension in the refrigerator. Shake well before each use. Consume the content (reconstituted) of **G-MOXIL CLAV 228.5 mg syrup** within 10 days .

CONTRAINDICATIONS
G-MOXIL CLAV is contraindicated in patients with penicillin hypersensitivity. Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics, e.g. cephalosporins. It is also contraindicated in patients with a previous history of **G-MOXIL CLAV** associated jaundice / hepatic

dysfunction.

PACKAGING INFORMATION

G-MOXIL CLAV 625mg tablets ……..Strip of 6 tablets

G-MOXIL CLAV 228.5 mg Syrup .....Bottle of 30Ml

G-MOXIL CV 375 mg Tablets ----------alu strip pack 6 tablets

G-MOXILCV DS 457 mg Syrup .....Bottle of 30mL