

**KEMOXYL 500 CAPSULES
(AMOXICILLIN CAPSULES.)**

MODULE 1

ADMINISTRATIVE INFORMATION AND PRESCRIBING INFORMATION

Kemoxyl®

COMPOSITION:

1. **Kemoxyl® 250mg capsules :**
Each capsule contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin 250mg.
2. **Kemoxyl® 500mg capsules :**
Each capsule contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin 500mg.
3. **Kemoxyl® Powder for oral Suspension 125mg/5ml :**
Each 5ml after reconstitution contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin 125mg.
4. **Kemoxyl® Forte Powder for oral Suspension 250mg/5ml :**
Each 5ml after reconstitution contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin 250mg.
5. **Kemoxyl®DT 125 Tablets :**
Each dispersible tablet contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin 125mg.
Contains Aspartame as a sweetener
6. **Kemoxyl®DT 250 Tablets :**
Each dispersible tablet contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin 250mg.
Contains Aspartame as a sweetener

PROPERTIES AND ACTIONS:

Kemoxyl® preparations contains Amoxicillin, an aminopenicillin antibacterial agent with bactericidal action. It acts on growing and dividing bacteria by inhibiting cell wall synthesis. It inhibits the final cross linking stage of peptidoglycan production by binding to and inactivating transpeptidases and penicillin-binding proteins on the inner surface of the bacterial cell membrane in addition to causing bacterial lysis by inactivation of endogenous inhibitors of bacterial autolysins.

Amoxicillin is resistant to inactivation by the acid of the gastric secretion. On oral administration Amoxicillin is rapidly absorbed and attains peak plasma concentration in about 1-2 hours. About 60% of the oral dose of Amoxicillin is excreted unchanged in the urine in 8 hours by glomerular filtration and tubular secretion.

INDICATIONS:

Kemoxyl® preparations are indicated for the treatment of infections caused by or associated with pathogens sensitive to Amoxicillin.

It is used in the treatment of respiratory tract infections such as bronchitis, pneumonia and tracheobronchitis. Amoxicillin preparations are also used in the treatment of bone and joint infections including Lyme's disease, biliary tract infections, actinomycosis, endocarditis, mouth infections, otitis media, spleen disorders, typhoid and paratyphoid fever, urinary tract infections including gonorrhoea and gastro-enteritis (including *Escherichia coli* and *Salmonella enteritis*).

DOSSAGE AND ADMINISTRATION:

Kemoxyl® preparations are administered by the oral route. Kemoxyl® powder are reconstituted to make 100ml or 60ml. Kemoxyl® DT Tablets are recommended to be dispersed in 5-10ml of water in order to form dispersion which is administered by the oral route

DOSE :

The usual dose of Amoxicillin is as follows:

Adult: 250 to 500mg every 8 hours, doubled in severe infections.

Children up to 18 years of age: 125mg to 250mg every 8 hours or 1 to 2 teaspoonfuls every 8 hours; doubled in severe infections.

Shake the bottle well before taking each dose.

The dose of Amoxicillin may vary depending on the disease, duration and severity of the infection

Diagnosis	Dose	
	Adults	Children
Severe or recurrent purulent respiratory infections	3g every 12 hours	2-5 years: 750mg every 12 hours 5-10 years: 1.5g every 12 hours
Otitis Media	-	750mg twice daily for 2 days
Urinary tract infections (UTI)	3g repeated after 10-12 hours	Single dose of 50mg/kg body wt. with 25mg/kg probenecid.
Gonorrhoea	Single dose of 2-3g with probenecid	1g Single dose of 50mg/kg with 25mg/kg probenecid.
Dental abscesses	1g repeated after 8 hours	-

AMOXICILLIN PREPARATIONS

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PRECAUTIONS, WARNING, CONTRA-INDICATIONS AND SIDE EFFECTS:

1. **Kemoxyl®** is contra-indicated in patients with known hypersensitivity to Amoxicillin or other penicillins.
2. Prolonged use of the preparation may result in overgrowth of non-susceptible pathogens including fungi and in such cases appropriate medication should be instituted immediately.
3. The side-effects occasionally associated with the preparations include: vomiting, nausea, diarrhea, rashes, pruritus, fever, urticaria and pseudomembranous colitis.
4. The treatment regimen which involves Amoxicillin and probenecid should be avoided in children under 2 years of age since probenecid is contraindicated in such children.

LEGAL CATEGORY: Prescription Only Medicines (POM), Schedule 2 (Botswana)

THERAPEUTIC CATEGORY: J01H (systemic antibiotics- penicillins)

STORAGE CONDITIONS: Store in a dry place below 30°C.

Protect from light.

Keep all medicines out of reach of children.

SHELF LIFE: As per product label.

PRESENTATION :

Kemoxyl® 250 capsules: Available in blister packs of 10 x 10's and bulk pack of 500's and 1000's.

Kemoxyl® 500 capsules: Available in blister packs of 10 x 10's and bulk pack of 500's and 1000's.

Kemoxyl® Powder for oral suspension: Available in bottles of 60ml and 100ml in unit box.

Kemoxyl® DT 125 tablets: Available in blister packs of 10 x 10's, 2 x 10's and bulk packs of 1000's.

Kemoxyl® DT 250 tablets: Available in blister packs of 10 x 10's, 1 x 10's, 2 x 10's and bulk packs of 1000's.

Date of Last Review: August 2020.

LICENCE HOLDER: LABORATORY & ALLIED LTD.

AMOXICILLIN PREPARATIONS



Manufactured by:

Laboratory & Allied Ltd.

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