

FYNALE

Nafdac N0. A4-1188

Artemether & lumefantrine Tablets

Each Tablet Contains:

Artemether	20 mg
Lumefantrine	120 mg
Excipient	q.s.

Indications: Treatment, including stand-by emergency treatment of adults and children with acute, uncomplicated infections due to *Plasmodium falciparum* or mixed infections including *P. falciparum*.

Dosage In Adult & Children Weighing 35 Kg & Above

A standard 3 days treatment schedule with a total of 6 doses is recommended as follows: Four tablets as a single dose at the time of initial diagnosis, again 4 tablets after 8 hours and then 4 tablets twice daily (morning and evening) on each of the following two days (total course comprises 24 tablets).

Stand By Emergency Treatment: For stand-by emergency treatment an intensive 3 days course is recommended, with four tablets as a single dose at the time of the onset of symptoms, again after 8 hours and then twice daily on each of the following two days (total course comprises 24 tablets).

Dosage In Children:

- 5-<15 kg bodyweight: One tablet at the time of initial diagnosis, and then 8, 24, 36, 48, and 60 hours thereafter (total course comprises 6 tablets.)
- 15-<25 kg body weight: Two tablets as a single dose at the time of initial diagnosis, and then 8, 24, 36, 48, and 60 hours thereafter (total course comprises 12 tablets).
- 25-<35kg bodyweight: Three tablets as a single dose at the time of initial diagnosis, and then 8, 24, 36, 48, and 60 hours thereafter (total course comprises 18 tablets)

Contraindication: FYNALE is contraindicated in patients hypersensitivity to the active substances or to any of the excipients.

- Patients with severe malaria according to WHO definition
- Patients with a family history of congenital prolongation of the QTC

Interval such as patients with a history of symptomatic cardiac arrhythmias, with clinically relevant bradycardia or with severe cardiac disease.

- Patients with known disturbances of electrolyte balance e. hypokalaemia or hypomagnesaemia.
- Patients taking any drug which is metabolized by the cytochrome enzyme CYP2D6 (e.g. flecainide, metoprolol, amitriptyline, clomipramine).
- Patients taking drugs that are known to prolong the Qtc interval such as antiarrhythmics of classes IA and III, neuroleptics, antidepressive agents, certain antibiotics including some agents of the following classes: macrolides, fluoroquinolones, imidazole, and triazole antifungal agents, certain non sedating antihistamines (terfenadine, astemizole), cisapride.