VEGARTEM-DS TABLETS

(Artemether 40 mg + Lumefantrine 240 mg)

COMPOSITION

Each tablet contains Artemether 40 mg and Lumefantrine 240 mg. Excipients: as per the approved formulation.

DESCRIPTION & PHARMACOLOGY

Artemether and lumefantrine form an artemisinin-based combination antimalarial (ACT). Artemether rapidly reduces the parasite burden; lumefantrine acts longer to eliminate remaining parasites. Both act against blood stages of malaria parasites.

INDICATIONS

Treatment of acute, uncomplicated malaria due to Plasmodium falciparum, including infections acquired in areas with chloroquine resistance, in accordance with locally approved indications and national malaria guidelines.

Not indicated for malaria prevention or as sole treatment of severe/complicated malaria. Severe malaria requires urgent parenteral treatment and specialist care.

DOSAGE & ADMINISTRATION

Oral administration with food or a milky drink to improve absorption. A complete course consists of SIX doses over THREE days: first dose at diagnosis (0 hours), second dose 8 hours later, then doses at approximately 24, 36, 48 and 60 hours.

Dosing is based on body weight, not merely age. Ensure enough tablets are dispensed for all six doses.

WEIGHT-BASED DOSING

For the 40 mg/240 mg tablet strength, the standard artemether/lumefantrine dose is:

15 to less than 25 kg: 1 tablet per dose, 6 doses; total 6 tablets.

25 to less than 35 kg: equivalent to 1.5 tablets per dose (60 mg/360 mg); use an appropriate alternative strength or formulation rather than assuming this tablet may be divided accurately.

35 kg and above: 2 tablets per dose, 6 doses; total 12 tablets.

Below 15 kg: use a suitable lower-strength paediatric formulation and follow the relevant approved dosing guidance.

PACK SIZE NOTE

Vegartem-DS is supplied as 8 tablets. One pack does NOT contain the full 12-tablet standard course for patients weighing 35 kg or more. Supply the complete prescribed quantity.

If vomiting occurs within one hour of administration, the dose generally needs repeating. If vomiting persists or oral therapy cannot be retained, seek urgent medical care.

CONTRAINDICATIONS

Hypersensitivity to artemether, lumefantrine or formulation components; concomitant use of strong CYP3A4 inducers such as rifampicin, carbamazepine, phenytoin or St John’s wort. Other contraindications may apply under the approved local label.

WARNINGS & PRECAUTIONS

Use caution in patients with congenital or acquired QT prolongation, clinically significant arrhythmias, bradycardia, electrolyte disturbances or concomitant QT-prolonging medicines. Evaluate cardiac risk and interacting medicines.

Absorption of lumefantrine is reduced without food, potentially increasing treatment failure. If food is poorly tolerated, administer as directed and monitor closely.

Recrudescence or recurrence of fever after therapy requires reassessment and parasitological testing. Do not use an incomplete treatment course.

DRUG INTERACTIONS

Avoid strong CYP3A4 inducers. CYP3A4 inhibitors and medicines prolonging the QT interval may increase adverse cardiac effects. Review antiretrovirals, macrolides, azole antifungals, antiarrhythmics, other antimalarials and hormonal contraceptive use.

PREGNANCY & LACTATION

Treatment during pregnancy should follow current malaria guidelines and individual benefit-risk assessment. Artemether/lumefantrine may be used when clinically indicated; untreated malaria itself presents substantial maternal and fetal risk. Breastfeeding decisions should follow approved local guidance and clinical assessment.

SPECIAL POPULATIONS

Use caution in patients with severe hepatic or renal impairment; data are limited. Clinical monitoring is appropriate.

ADVERSE REACTIONS

Reported effects include headache, dizziness, weakness, loss of appetite, nausea, vomiting, abdominal pain, sleep disturbance, muscle or joint pain and palpitations. Rare serious reactions include hypersensitivity and cardiac rhythm disturbances.

OVERDOSAGE

Seek emergency medical attention after suspected overdose. Supportive care, clinical observation, ECG and electrolyte monitoring may be needed. No specific antidote is established.

STORAGE CONDITIONS

Store according to the approved product specification, protected from excessive heat and moisture. Keep out of reach of children. Do not use after expiry.

PRESENTATION

Vegartem-DS Tablets: each tablet contains Artemether 40 mg + Lumefantrine 240 mg. Pack of 8 tablets.

PATIENT ADVICE

Take with food or milk and complete all six doses even if symptoms improve. Do not miss doses. Contact a healthcare professional promptly if vomiting persists, fever returns, fainting or palpitations occur, or the patient becomes seriously unwell.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.