NOVARTIS

RIAMET® (artemether/lumefantrine)

20 mg/120 mg tablets

Basic Succinct Statement (BSS)

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This material is only meant for Healthcare Professionals

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RIAMET®

Important note: Before prescribing, consult full prescribing information.

Presentation: Fixed combination: tablets for oral administration containing 20 mg artemether and 120 mg lumefantrine

Indications: Treatment and standby emergency treatment of adults and children with infections due to *Plasmodium falciparum* or mixed infections including *P.falciparum*. Because Riamet is effective against both drug-sensitive and drug-resistant *P.falciparum* it is also recommended for malaria infections acquired in areas where the parasites may be resistant to other antimalarials.

Dosage for treatment and standby emergency treatment: Tablets to be taken with food or drinks rich in fat (e.g. milk).

Adults: Four tablets as a single dose at the time of initial diagnosis, and then 8, 24 and 48 hours thereafter (total course comprises 16 tablets).

Treatment in multi-drug-resistant areas and non-immune patients:

In areas of multi-drug-resistant malaria (e.g. Thailand) and in non-immune patients an intensive 3-day course is recommended, with four tablets as a single dose at the time of initial diagnosis, again after 8 hours and then twice daily on each of the following two days (total course comprises 24 tablets).

Stand-by emergency treatment:

For stand-by emergency treatment an intensive 3-day course is recommended, with one to three tablets (depending on bodyweight) given 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 6, 12 or 18 tablets depending on bodyweight).

10-<15kg bodyweight: One tablet 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 6 tablets).

15-<25kg bodyweight: Two 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 12 tablets).

25-<35kg bodyweight: Three 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 18 tablets).

Dosage in elderly patients

Although no studies have been carried out in the elderly, no special precautions or dosage adjustments are considered necessary in such patients.

Dosage in patients with renal or hepatic impairment

Although no specific studies have been carried out, no special precautions or dosage adjustments are considered necessary for these conditions.

Most patients with acute malaria present with some degree of related hepatic impairment. The adverse event profile did not differ in patients with and those without hepatic impairment.

Moreover, baseline abnormalities in liver function tests improved in nearly all patients after treatment with Riamet.

New and recrudescent infections in adults and children

Data for a limited number of patients show that new and recrudescent infections can be treated with a second course of Riamet. In-vitro studies involving samples from patients with recrudescent infection showed no significant decrease in the sensitivity of *P.falciparum* to either artemether or lumefantrine. In the absence of carcinogenicity study data, and due to lack of clinical experience, more than two courses of Riamet cannot be recommended.

Contraindications: Known hypersensitivity to the active substances or any of the excipients. ♦Severe malaria. ♦Cardiac arrhythmia, bradycardia, severe cardiac diseases, QTc prolongation, family history of sudden death. ♦Disturbances of electrolyte balance, e.g. hypokalaemia or hypomagnesaemia. ♦Concomitant use of drugs that are known to be metabolised by cytochrome enzyme CYP2D6 or drugs that are known to prolong the QTc interval. ♦Concomitant use with drugs that are strong inducers of CYP3A4 such as rifampicin, carbamazepine, phenytoin, St. John's Wort.

Warnings and precautions: Not indicated for prophylactic use. Not recommended for severe malaria. Should not be used in the 1st trimester of pregnancy in situations where other suitable and effective antimalarials are available. Caution in patients with severe hepatic or renal insufficiency, patients refusing food intake, and patients during 2nd and 3rd trimester of pregnancy. Not to be given concurrently with other antimalarials unless no other treatment option. Special care with patients previously treated with halofantrine.

Adverse drug reactions: When frequency difference between adults and children, higher frequency reported here. **Very common (>10%)**: decreased appetite, sleep disorder, headache, dizziness, palpitations, abdominal pain, vomiting, nausea, arthralgia, myalgia, asthenia, fatigue. **Common (1 to 10%)**: clonus, cough, diarrhoea, pruritus, rash, increased liver function tests. **Less frequent (<1%) but (potentially) serious**: somnolence, QTc prolongation. **Adults only** (uncommon): hypoaesthesia, gait disturbance, ataxia. **Post-marketing:** hypersensitivity reactions, including urticaria and angioedema.