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## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE MEDICINAL PRODUCT**

#### **SHAL'ARTEM**

Composition:

Each 60 ml contains when reconstituted:

Artemether 180 mg and Lumefantrine 1080 mg

Pharmaceutical form:

Powder for reconstitution for suspension

### **2. Qualitative and Quantitative Composition**

Artemether.....180mg

Lumefantrine.....1080mg

For a full list of excipients, see section 6.1.

### **3. Pharmaceutical form**

Powder for reconstitution for suspension,

Light yellow coloured free flowing powder, after reconstitution yellow coloured suspension.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

SHAL'ARTEM is indicated for the treatment of malaria in children, caused by all forms of plasmodium including severe malaria caused by multiple drug resistant strains of *P. falciparum*.

#### **4.2 Posology and Method of Administration**

SHAL'ARTEM (Artemether and Lumefantrine Dry Syrup) has especially been designed for use in children.

The dose depends on the severity of the case and the clinical situation of the patient

#### **Directions for reconstitution of SHAL'ARTEM Dry Syrup:**

Take boiled and cooled water and add it slowly up to the ring mark present on the bottle.

Shake the bottle and if necessary adding more water to adjust the volume up to the ring mark this makes 60 ml of SHAL'ARTEM Dry Syrup.

Use the SHAL'ARTEM Dry Syrup within 7 days after reconstitution. Shake the bottle every time before use.

A standard 3-day treatment schedule, with a total of 6 doses, is recommended as follows.

Chil	Day 1	Day 2	Day 3
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body weight			Morning	Evening	Morning	Evening
5-less than 15kg	At 0 hour	8 hours	24 hours	36 hours	48 hours	60 hours
	7ml	7ml	7ml	7ml	7ml	7ml

SHAL'ARTEM Dry Syrup should be taken with foods or drinks having high quantity of fat such as milk.

If vomiting occurs within one hour of taking SHAL'ARTEM Dry Syrup a repeat dose should be taken.

### 4.3 Contraindications

SHAL'ARTEM is contraindicated in those with hypersensitivity to the active substances or any of the excipients, in the first trimester of pregnancy, patients with a family history of congenital prolongation of the QTc interval or sudden death or with any other clinical condition known to prolong the QTc interval such as patients with a history of symptomatic cardiac arrhythmias, patients with clinically relevant bradycardia or with severe cardiac disease, family history of sudden death, disturbances of electrolyte balance, e.g. hypokalaemia or hypomagnesaemia.

SHAL'ARTEM is not indicated for prophylaxis of malaria.

### 4.4 Special warnings and precautions for use

Use with caution in patients with severe hepatic or renal insufficiency and patients refusing food intake. Patients who remain averse to food during treatment should be closely monitored as the risk of recrudescence may be greater.

### 4.5 Interaction with other medicinal products and other forms of interaction

The sequential oral administration of mefloquine prior to artemether and lumefantrine combination had no effect on plasma concentrations of artemether or the artemether/ dihydroartemisinin (DHA) ratio but

there was a significant (around 30-40%) reduction in plasma levels (Cmax and AUC) of lumefantrine, possibly due to lower absorption secondary to a mefloquine-induced decrease in bile production. Such

patients should therefore be encouraged to eat at dosing times to compensate for this decrease in bioavailability. Quinine alone caused a transient prolongation of the QTc interval, which was consistent with its known cardiotoxicity. This effect was slightly but significantly greater when quinine was infused after artemether and lumefantrine combination. Hence when artemether and lumefantrine combination is given to patients following administration of mefloquine or quinine, close monitoring of food intake (for mefloquine) or the ECG (for quinine) should be carried out. In patients previously treated with halofantrine, L- Artem should be administered at least one month after the last halofantrine dose.

Due to limited data on safety and efficacy, the combination should not be given concurrently with other antimalarial unless there is no other treatment option.

However, if a patient deteriorates while taking the combination, alternative treatments for malaria should be commenced without delay. In such cases, monitoring of the ECG is recommended and steps should be taken to correct electrolyte disturbances.

#### **4.6 Pregnancy and lactation**

This product is intended for children only.

#### **4.7 Effects on ability to drive and use machines**

Driving and use of machinery is not recommended because SHAL'ARTEM Dry Syrup may cause impairment in balance.

#### **4.8 Undesirable effects**

Common adverse events reported with artemether and lumefantrine combination included headache, dizziness, sleep disorder, abdominal pain, anorexia, diarrhea, vomiting, nausea, palpitation, cough, arthralgia, myalgia, pruritus, rash, asthenia and fatigue.

Somnolence, involuntary muscle contractions, paraesthesia, hypoaesthesia, abnormal gait, ataxia were other adverse effects reported with artemether and lumefantrine combination.

Rare adverse event included hypersensitivity.

Unspecified personality disorders have also been reported in children <5 years treated with artemether and lumefantrine combination.

#### **4.9 Overdose**

In cases of suspected overdosage, symptomatic and supportive therapy should be given as appropriate. ECG and blood potassium levels should be monitored.

### **5.1 Pharmacodynamic Properties**

SHAL'ARTEM is a fixed dose artemisinin-based combination therapy (ACT) combining Artemether, an artemisinin derivative, and Lumefantrine, a synthetic antimalarial drug.

Both Artemether and Lumefantrine act as blood schizontocides. The site of anti-parasitic action of both components of the combination is the food vacuole of the malarial parasite, where they are thought to interfere with the conversion of haem, a toxic intermediate produced during haemoglobin breakdown, to the non-toxic haemozoin, malaria pigment.

### **5.2 Pharmacokinetic Properties**

Artemether is absorbed fairly rapidly with peak plasma concentrations reached about 2 hours after dosing. Absorption of Lumefantrine, a highly lipophilic compound, starts after a lag period of up to 2 hours, with peak plasma concentration about 6-8 hours after dosing. Food enhances the absorption of both Artemether and Lumefantrine. Artemether and Lumefantrine are both highly bound to human serum proteins in vitro (95.4% and 99.7%, respectively). The artemisinin metabolite dihydroartemisinin is also bound to human serum proteins (47%-76%). Artemether is rapidly and extensively metabolised by human liver microsomes. The

main active metabolite is dihydroartemisinin. Lumefantrine is also metabolised predominantly by the enzyme CYP3A4 in human liver microsomes. Artemether and dihydroartemisinin are rapidly cleared from plasma with an elimination half-life of approximately 2-3 hours.

Conversely, Lumefantrine is eliminated very slowly with a terminal half-life of 2-3 days in healthy volunteers and 4-6 days in patients with falciparum malaria. No urinary excretion data are available for humans.

### **5.3 Preclinical safety data**

No preclinical findings of relevance have been reported.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Carmellose Sodium BP, Sucrose BP, Sodium methyl hydroxybenzoate BP, Sodium propyl hydroxybenzoate BP, Anhydrous Citric Acid BP, Saccharin Sodium BP, Colloidal Anhydrous Silica BP and Flavour Pineapple DM.

### **6.2 Incompatibilities**

None known

### **6.3 Shelf life**

36 months

### **6.4 Special precautions for storage**

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

### **6.5 Nature and contents of the container**

60ml HDPE bottle with 10ml measuring cup packed in a carton along with a leaflet.

### **6.6 Special precautions for disposal and other handling**

None

## **7. MARKETING AUTHORIZATION HOLDER**

### **M/s SHALINA HEALTHCARE DMCC**

30<sup>th</sup> Floor, Almas Towers, Jumeirah Lakes Towers,  
Dubai-UAE. Country: Dubai

## **8. MARKETING AUTHORIZATION NUMBER**

H2015/CTD647/306.

## **9. DATE OF FIRST REGISTRATION /RENEWAL OF THE <REGISTRATION>**

**Date of first authorization:** 27<sup>th</sup> Oct.2015

**Date of latest renewal:** Renewal application

## **10. DATE OF REVISION OF TEXT**

31/03/2026