### 1.3.1 Summary of Product Characteristics (SmPC)

## 1. NAME OF THE MEDICINAL PRODUCT

**OGAMAL QS SOFTGELS** (Softgels Artemether and Lumefantrine)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft gelatin capsule contains:
Artemether Ph.Int…… 80 mg

Lumefantrine Ph.Int…. 480 mg

## 3. PHARMACEUTICAL FORM

Soft Gelatin Capsules

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the treatment of most forms and resistant types of malaria.

### 4.2 Posology and method of administration

**Dosage in Adult Patients (>16 years of age)**
A 3-day treatment schedule with a total of 6 doses is recommended for adult patients with a bodyweight of 35 kg and above.
One capsule as an initial dose, 1 capsule again after 8 hours and then 1 capsule twice daily (morning and evening) for the following two days (total course of 6 capsules).

**DO NOT EXCEED THE DOSAGE PRESCRIBED**

| Weight in Kgs | Total Capsules | Dosage Regimen | | | | | |
|---|---|---|---|---|---|---|---|
| | | Day - 1 | | Day - 2 | | Day – 3 | |
| 35 kg-above | 6 | 0 Hours (Initial dose) | 8 Hours (after 1st dose) | 24 Hours | 36 Hours | 48 Hours | 60 Hours |
| | | 1 Capsule | 1 Capsule | 1 Capsule | 1 Capsule | 1 Capsule | 1 Capsule |

**4.3 Contraindications:**

- Hypersensitivity to any of the ingredients
- Patients who are taking any drug which is metabolized by the cytochrome enzyme CYP2D6 (e.g. flecainide, metoprolol, imioramine, amitryptiline, clomipramine).
- Patients with disturbances of electrolyte balance eg hypokalemia.

**4.4 Special warnings and precautions for use**

- It must not be used in first Trimester of Pregnancy.
- It has not been evaluated for the treatment of severe malaria.
- For the treatment of most forms and resistant types of malaria.

**4.5 Fertility, pregnancy and lactation**

**Pregnancy**

There is insufficient data from the use of artemether and lumefantrine in pregnant women. Based on animal data, it is suspected to cause serious birth defects when administered during the first trimester of pregnancy. During second and third trimester, treatment should only be considered if the expected benefit to the mother outweighs the risk to the fetus.

**Lactation**

Animal data suggest excretion into breast milk but no data are available in humans. Women taking the product should not breast-feed during their treatment. Due to the long elimination half-time of lumefantrine (4 to 6 days), it is recommended that breastfeeding should not resume until at least one week after the last dose unless potential benefits to the mother and child outweigh the risks of treatment.

**4.6 Effects on ability to drive and use machines**

No studies on the effect on the ability to drive and use machines have been performed.

## 5. PHARMACOLOGICAL PROPERTIES

**5.1 Pharmacodynamic properties**

**ARTEMETHER**

In the body, artemether is metabolized into the active metabolite metabolite dihydroartemisinin. The drug works against the erythrocytic stages of P. falciparum by inhibiting nucleic acid and protein synthesis. Artemether is administered in combination with lumefantrine for improved efficacy. Artemether has a rapid onset of action and is rapidly cleared from the body. It is thought that artemether provides rapid symptomatic relief by reducing the number of malarial parasites. Lumefantrine has a much longer half life and is believed to clear residual parasites.

**LUMEFANTRINE**

Lumefantrine is a blood schizonticide active against erythrocytic stages of Plasmodium falciparum. It is thought that administration of lumefantrine with artemether results in cooperate antimalarial clearing effects. Artemether has a rapid onset of action and is rapidly cleared from the body. It is thus thought to provide rapid symptomatic relief by reducing the number of malarial parasites. Lumefantrine has a much longer half life and is believed to clear residual parasites**.**

**5.2 Pharmacokinetic properties**

**ARTEMETHER**

Absorption of artemether is improved 2- to 3-fold with food. It is highly bound to protein (95.4%). Peak concentrations of artemether are seen 2 hours after administration.

Artemether is metabolized in the human body to the active metabolite, dihydro-artemisinin, primarily by hepatic enzymes CYP3A4/5. Both the parent drug and active metabolite are eliminated with a half-life of about 2 hours.

**LUMEFANTRINE**

Bio-availability after oral administration is variable; absorption is substantially increased by co-administration with food, particularly with a high fat content. Peak plasma concentrations occur after 6–8h. The elimination half-life is 4–6 days. It is almost completely protein bound and metabolised mainly in the liver by CYP3A4.

### 5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, genotoxicity and toxicity to reproduction.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

| S. No. | Ingredients | Specification |
|---|---|---|
| 1. | Refined Corn Oil | USP |
| 2. | Hydrogenated Vegetable Oil | BP |
| 3. | White Bees Wax | BP |
| 4. | Butylated Hydroxy Anisole | BP |
| 5. | Butylated Hydroxy Toluene | BP |
| 6. | Soyalecithin | USP |
| 7. | Methyl Paraben | BP |
| 8. | Propyl Paraben | BP |

### 6.2 Incompatibilities

None known.

### 6.3 Shelf – life:

24 months from the date of manufacturing.

### 6.4 Special precautions for storage:

Store below 30°C in a cool & dry place,
Protect from direct light, heat & moisture.

Keep out of reach of children.

**6.5 Nature and contents of container :**

6 Capsules packed in Alu-PVC Blister Pack, 1 Blisters packed in mono carton along with package insert and 10 Mono Cartons are packed in 1 Outer Carton.

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

Not applicable

**7. MARKETING AUTHORIZATION HOLDER:** NA

**8. MANUFACTURER:**

**ASOJ SOFT CAPS PVT. LTD.**
Asoj, Baroda – Halol Highway,
Dist. Baroda – 391 510. Gujarat.

8, Marketing Authorization Holder
Lifeback Pharmacy and Stores Limited,
Ebutte-Metta, Lagos.