1.3.1 Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

DAICITEM (Softgels Artemether and Lumefantrine)

1.1 STRENGTH

EACH SOFT GELATIN CAPSULE CONTAINS:

Artemether	Ph.Int	20 mg
Lumefantrine	Ph.Int	120 mg
Excipients		q.s.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ASOJ SOFT CAPS PVT. LTD

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Baroda-Halol Highway, Dist - Baroda - 391 510

Product Brand Name : DAICITEM		
Product Generic Name : Softgels of Artemether & Lumefantrine		
Title: COMPOSITION SHEET OF RAW MATERIAL		
		Sheet D
		Product code CSG2049
Date	Mfg. For	Colour: Green Opaque
Mfg. For	Mfg. Date	Fill weight : 290 mg +/- 29 MG (R.L.)
Batch Size 200000	Exp. Date	Die: Oval
Revision No. : New	Shelf Life : 2 Years	Page No. : 1

Sr. No.	Name of Raw Material	Specification	Wt per cap (mg)	O.A. % Per Caps	Qty. per caps with O.A. % (mg)	Total Qty per Batch kg (A)	Purity	Actual Qty req. per batch (B)
	MEDICINE COMPOSITION							
(A)	Active ingredients							
1	Arthemether	Ph.Int	20.000	10	22.00	4.4		
2	Lumefantrine	Ph.Int	120.000	10	132.00	26.4		
	Excipients							
3	Refined Corn Oil	U.S.P.	15.740	0	15.74	3.148		*
4	Hydrogenated Vegetable Oil	B.P.	40.000	0	40.00	8		
5	White Bees Wax	B.P.	75.000	0	75.00	15		
6	Soya Lecithin	U.S.P.	5.000	0	5.00	1		
7	Butylated Hydroxy Anisole	B.P.	0.100	0	0.10	0.02		
8	Butylated Hydroxy Toluene	B.P.	0.050	0	0.05	0.01		
9	Methyl Paraben	B.P.	0.100	0	0.10	0.02		
10	Propyl Paraben	B.P.	0.010	0	0.01	0.002		
	TOTAL FILL WEIGHT PER CAPS				290.00			
	TOTAL WT OF BATCH SIZE IN KG					58		

* = A (3) - [Total of B (1 to 2) - Total of A (1 to 2)] =

Note: Quantity of Refind corn oil (U.S.P) adjusted increased quantity of active raw material as on 100% purity basis so as to make total quantity as per batch size i.e._____ kg

Prepared By :	Checked By :	Approved By :

ASOJ SOFT CAPS PVT. LTD. * BARODA *

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 of35 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.

4.6 **Fertility, pregnancy and lactationPregnancy**

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.

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

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

4.9 Overdose: Not Provided

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, dihydroartemisinin, primarily by hepatic enzymes CYP3A4/5. Both the parent drug and active metabolite are eliminated with a half-life of about 2 hours.

LUMEFANTRINE

Bioavailability 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 metabolized 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 :**

12 Capsules packed in Alu-PVC Blister Pack, 1 Blisters packed in carton along with package insert.

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

Not applicable

7. MARKETING AUTHORIZATION HOLDER:

DAITECH PHARMACEUTICALS LTD.
[redacted]
ZONE 2, ABUJA

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