1.3.1
Summary Of Product Characteristics (SPC)

1.3 PRODUCT INFORMATION

1.3.1 Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

FYNALE FORTE-SG (Softgels of Artemether & Lumefantrine)

1.1 STRENGTH

Each Soft Gelatin Capsule Contains:

Artemether	Ph.Int.	80 mg
Lumefantrine	Ph.Int.	480 mg
Excipients		q.s.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ASOJ SOFT CAPS PVT. LTD

[illegible] Highway, [illegible]

Product Brand Name : FYNALE FORTE-SG		
Product Generic Name : Softgels of Artemether & Lumefantrine		
Title: COMPOSITION SHEET OF RAW MATERIAL		Sheet: D
		Product Code : CSG3370
Date :	Mfg. For :	Colour: Orange Opaque
Mfg. For :	Mfg. Date :	Fill weight: 1100 MG +/- 82 MG (R.L.)
Batch Size: 550000	Exp. Date :	Dia: 20 A Oval
Revision No. : New	Shelf Life :	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	Artheamether	Ph.Int	80	10	88	48.4		
2	Lumefantrine	Ph.Int	480	5	504	277.2		
	Excipients							
3	Refined Corn Oil	U.S.P.	224.8	0	224.8	123.64		*
4	Hydrogenated Vegetable Oil	B.P.	80	0	80	44		
5	White Bees Wax	B.P.	150	0	150	82.5		
6	Soya Lecithin	U.S.P.	53	0	53.0	29.15		
7	Butylated Hydroxy Anisole	B.P.	0.1	0	0.1	0.055		
8	Butylated Hydroxy Toluene	B.P.	0.05	0	0.05	0.0275		
9	Methyl Paraben	B.P.	0.1	0	0.1	0.055		
10	Propyl Paraben	B.P.	0.01	0	0.01	0.0055		
	TOTAL FILL WEIGHT PER CAPS				1,100			
	TOTAL WT OF BATCH SIZE IN KG					605		

* = 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 materials as on 100% purity basis so as to make total quantity as per batch size i.e. _____ kg.

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 35kg 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, imipramine, amitryptiline, clomipramine).
- Patients with disturbances of electrolyte balance eghypokalaemia.

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 breastfeed 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, 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 :

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.

Inner Carton Size: L-130 x W-14 x H-72 mm

Fynale Forte SG

Softgels of Artemether & Lumefantrine

Each Soft Gelatin Capsule Contains:

Artemether	Ph. Int.	80 mg
Lumefantrine	Ph. Int.	480 mg
Excipients		q.s.

Approved colours used in capsule shell.

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

Read the pack insert carefully.

KEEP OUT OF REACH OF CHILDREN

Manufactured in India by :
ASOJ SOFT CAPS PVT. LTD.
Asoj, Baroda-Halol Highway,
Dist. Baroda - 391 510. Gujarat.

Marketed by :
Aquatix Pharmaceuticals Limited
Lagos, Nigeria.

NAFDAC Reg. No.:

Mfg. Lic. No.: G/607

Batch No.:

Mfg. Date :

Exp. Date :

Dosage:

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

Space for barcode

Fynale Forte SG
Softgels of Artemether & Lumefantrine

Fynale Forte SG
Softgels of Artemether & Lumefantrine

Fynale Forte SG
Softgels of Artemether & Lumefantrine

6 Softgels

Fynale Forte SG
Softgels of Artemether & Lumefantrine

Aquatix

Fynale Forte SG
Softgels of Artemether & Lumefantrine

Size : 155 x 76 x 134 mm

10 x 1 x 6 Softgels

Fynale Forte SG
Softgels of Artemether & Lumefantrine

Aquatix

Fynale Forte SG
Softgels of Artemether & Lumefantrine

10 x 1 x 6 Softgels

Fynale Forte SG
Softgels of Artemether & Lumefantrine

Aquatix

Fynale Forte SG
Softgels of Artemether & Lumefantrine

NAFDAC Reg. No.:
Mfg. Lic. No.: G/607
Batch No.:
Mfg. Date :
Exp. Date :

Space for barcode

Marketed by :
Aquatix Pharmaceuticals Limited
Lagos, Nigeria.

Foil size : 131 mm

Foil Size - 131 mm, single track, black matter