# SUMMARY OF PRODUCT CHARACTERISTICS
## COFANART 20/120 (Artemether 20 mg / Lumefantrine 120 mg Tablets)

## 1. NAME OF THE MEDICINAL PRODUCT

COFANART 20/120 (Artemether 20 mg / Lumefantrine 120 mg Tablets)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains artemether 20 mg and lumefantrine 120 mg.

**Excipients with known effect:**

Each tablet contains lactose 66 mg, aspartame (E951) 7 mg and sodium benzoate (E211) 0.5 mg. This medicinal product contains less than 1 mmol sodium (23 mg) per tablet — essentially sodium-free. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Tablet (uncoated).

Yellow coloured, round-shaped, uncoated tablet with a break line on one side and plain on the other side.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

COFANART 20/120 is indicated for the treatment of acute uncomplicated Plasmodium falciparum malaria in adults, children and infants of 5 kg body weight and above. Consideration should be given to official guidance regarding appropriate use of antimalarial agents.

### 4.2 Posology and method of administration

**Adults and children weighing ≥35 kg (≥12 years and ≥35 kg)**

A 6-dose regimen: 4 tablets per dose. First dose at time of initial diagnosis; followed by 5 further doses of 4 tablets given at 8, 24, 36, 48 and 60 hours. Total: 24 tablets over 60 hours.

**Children and infants (5 kg to <35 kg)**

5 to <15 kg: 1 tablet per dose × 6 doses (8, 24, 36, 48, 60 hours after first dose). 15 to <25 kg: 2 tablets per dose × 6 doses. 25 to <35 kg: 3 tablets per dose × 6 doses.

**Infants <5 kg**

Safety and efficacy not established; no dosing recommendations.

**Method of administration**

Oral. To increase absorption, COFANART should be taken with food or a milky drink. If the patient cannot tolerate food, administer with water. Patients who vomit within 1 hour of taking the medication should repeat the dose. For administration to small children and infants, the tablet(s) may be crushed. If elderly patients are involved, no dose adjustment is required.

### 4.3 Contraindications

- Hypersensitivity to artemether, lumefantrine or to any of the excipients listed in section 6.1.
- Severe malaria according to WHO definition.
- Concomitant use with drugs metabolised by CYP2D6 (e.g. metoprolol, imipramine, amitriptyline, clomipramine).
- Family history of sudden death or of congenital prolongation of the QTc interval, or any other clinical condition known to prolong the QTc interval.
- Concomitant use with drugs known to prolong the QTc interval (class IA and III antiarrhythmics, neuroleptics, antidepressants and certain anti-infectives including macrolides, fluoroquinolones and some antifungals).
- Concomitant use with antimalarials unless there is no other option.

## 4.4 Special warnings and precautions for use

**Cardiac safety / QTc prolongation**

Lumefantrine inhibits hERG channels and has been associated with QTc prolongation. Caution is required in patients with: electrolyte disturbances (hypokalaemia, hypomagnesaemia); concomitant use of drugs that prolong the QTc interval; cardiac conditions including pre-existing QTc prolongation. An ECG should be performed before and during treatment in high-risk patients.

**Severe malaria**

COFANART is not indicated for severe malaria. Patients with severe malaria should receive appropriate parenteral antimalarial therapy.

**Phenylketonuria**

This product contains aspartame, a source of phenylalanine (3.5 mg per tablet). Patients with phenylketonuria must be informed.

**Lactose**

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**Sodium benzoate**

This product contains sodium benzoate, a mild irritant. Not recommended for use in neonates (<28 days).

**Drug interactions**

Do not use with other antimalarials unless there is no other option. Lumefantrine is partly metabolised by CYP3A4; inducers (e.g. rifampicin, carbamazepine, St. John's Wort) may reduce its efficacy. CYP3A4 inhibitors (e.g. ketoconazole, ritonavir) may increase lumefantrine exposure. Grapefruit juice may increase lumefantrine exposure and should be avoided.

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

CYP2D6 substrates (e.g. metoprolol, antidepressants): Lumefantrine inhibits CYP2D6; co-administration is contraindicated. QTc-prolonging drugs (class IA/III antiarrhythmics, haloperidol, certain fluoroquinolones, macrolides, azole antifungals): contraindicated or use with extreme caution. CYP3A4 inducers (rifampicin, carbamazepine, phenytoin, St. John's Wort): may reduce lumefantrine plasma concentrations and efficacy. Grapefruit juice: may increase lumefantrine bioavailability; avoid. Antacids and drugs that raise gastric pH: may reduce artemether and/or lumefantrine absorption.

## 4.6 Fertility, pregnancy and lactation

**Pregnancy**

Limited data on use in pregnancy. Animal data show reproductive toxicity at high doses. COFANART should be used in pregnancy only if the expected benefit outweighs the risk. The WHO currently recommends artemether/lumefantrine for uncomplicated P. falciparum malaria in the second and third trimesters of pregnancy.

**Breast-feeding**

It is not known whether artemether or lumefantrine is excreted in human breast milk. A risk to the breastfed infant cannot be excluded. A decision should be made whether to discontinue breast-feeding or discontinue COFANART.

**Fertility**

No information on effects on human fertility is available.

## 4.7 Effects on ability to drive and use machines

COFANART may cause dizziness, headache and sleep disorders, which may affect the ability to drive and operate machines. Patients should be advised to take caution.

## 4.8 Undesirable effects

Very common: Sleep disorders, headache, nausea. Common: Dizziness, palpitations, anorexia, abdominal pain, diarrhoea, vomiting, myalgia, arthralgia, rash, pruritus, fatigue, cough, rhinitis. Uncommon: Elevated liver function tests. Cardiac arrhythmias (including QTc prolongation) have been reported.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

### 4.9 Overdose

In case of overdose, symptomatic treatment should be given, with particular attention to the patient's cardiac status (ECG monitoring). There is no specific antidote.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiprotozoals, antimalarials. ATC code: P01BF01.

Artemether is a semi-synthetic endoperoxide derivative of artemisinin. It acts by interfering with the haem detoxification process in the malaria parasite (Plasmodium spp.). Artemether is a rapid-acting blood schizonticide. Lumefantrine is a racemic fluorene derivative. It inhibits the formation of β-haematin by forming a complex with haemin, disrupting parasite membrane structure. The combination of artemether (fast-acting) and lumefantrine (longer half-life) provides both rapid parasite clearance and a sustained effect that reduces the risk of recrudescence.

### 5.2 Pharmacokinetic properties

Artemether: Rapidly absorbed after oral administration with a high-fat meal; Tmax approximately 2 hours. Extensively metabolised to active metabolite dihydroartemisinin (DHA). Half-life of artemether approximately 2 hours; DHA approximately 4–5 hours. Lumefantrine: Absorbed slowly and erratically if taken without food; absorption increases approximately 16-fold with a fat-containing meal. Highly protein-bound. Tmax 6–8 hours. Half-life approximately 3–6 days (terminal). Metabolised primarily by CYP3A4 to active metabolite desbutyl-lumefantrine.

### 5.3 Preclinical safety data

The combination showed acceptable safety in non-clinical studies. Lumefantrine showed CNS effects at high doses in dogs; cardiovascular effects (QTc prolongation) observed in in vitro and in vivo studies consistent with hERG channel inhibition. Artemether is embryotoxic and teratogenic in animals at doses near the therapeutic range; use with caution in early pregnancy.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Kyron T-314 (cross-linked polyacrylic acid) BP, sodium lauryl sulfate BP, lactose BP (66 mg per tablet; excipient with known effect), povidone K-30 BP, sodium benzoate BP (E211; 0.5 mg per tablet; excipient with known effect), polysorbate-80 BP, purified water BP (manufacturing solvent), magnesium stearate BP, purified talc BP, colloidal anhydrous silica BP, croscarmellose sodium BP, aspartame BP (E951; 7 mg per tablet; excipient with known effect), mixed fruit dry powder flavouring BP.

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

36 months.

### 6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

### 6.5 Nature and contents of container

24 tablets packed in one ALU-PVC blister. 1 blister per carton with package insert.

### 6.6 Special precautions for disposal and other handling

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

**ZAIN PHARMA LTD.**
Plot No. 209/13741, Colchester Park,
Go-Down No. 1, 2, 3, Off Mombasa Road,
Behind Nice and Lovely House,
P.O. Box: 100167-00101, Nairobi, Kenya.

## 8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD11750/24999

## 9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

23.03.2026

## 10. DATE OF REVISION OF THE TEXT

23.03.2026