SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Co-Arinate FDC Junior - Fixed dose combination of Artesunate-Sulfamethoxypyrazine-Pyrimethamine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains
Artesunate.....100 mg
Sulfamethoxypyrazine .....250 mg
Pyrimethamine.....12.5 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Box containing 1 blister of 3 tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Co-Arinate FDC is used as curative treatment for all forms of malaria, including severe malaria caused by multi-drug resistant strains of Plasmodium falciparum. In case of P. vivax, addition of primaquine may be required. Co-Arinate FDC has been especially designed to treat malaria in children, adolescents and adults.

4.2 Posology and method of administration

Dose is based on body weight at 4 mg/kg of Artesunate combined with Sulfamethoxypyrazine and Pyrimethamine. Treatment must be administered three times within a period of 48 hours: first tablet upon confirmation of malaria diagnosis (Time 0), second tablet 24 hours later, and final tablet after a further 24 hours (24-hour interval between doses must be adhered to).

Dosage scheme: For weight ≥10kg to <18kg (1-5 years): 1/2 tablet at 0h, 24h, and 48h (total 1.5 tablets). For weight ≥18kg to <36kg (6-13 years): 1 tablet at 0h, 24h, and 48h (total 3 tablets). Tablets should be taken with fluid such as drinking water and may be crushed if necessary. A full course of therapy is essential to avoid recrudescence.

In case of vomiting within 30 minutes after intake, the full dose should be re-administered. Vomiting within 1 hour after intake requires re-administering half the dose. A further course may be necessary if malaria returns (relapse) or if reinfected with Plasmodium parasites after being cured.

4.3 Contraindications

Contraindicated in individuals hypersensitive to Artesunate, Sulfamethoxypyrazine, Pyrimethamine or any other ingredient. Contraindicated in severe hepatic or renal insufficiency, severe blood dyscrasias, or documented megaloblastic anaemia due to folate deficiency.

4.4 Special warnings and precautions for use

Inform the doctor of other medicines taken or medical problems present. It is essential for patients to complete the full treatment to avoid recrudescence. In case of complicated malaria, general medical supportive care should be provided.

4.5 Interactions with other medicinal products

Artesunate

No clinically significant adverse drug interactions reported to date. The activity of other anti-malarials may be potentiated by Artesunate.

Sulfamethoxypyrazine and Pyrimethamine

Antifolic acid drugs such as other sulfonamides or trimethoprim-sulfamethoxazole combinations should not be used while the patient is receiving this combination for antimalarial treatment.

4.6 Pregnancy and lactation

Pregnancy

Use is not recommended during the first trimester (organogenesis period) unless, in the doctor's opinion, the benefits outweigh the risks, as is often encountered with complicated and cerebral malaria. No cases of human embryotoxicity or teratogenicity have been reported.

Breastfeeding

Women should not breastfeed their infants during Co-Arinate FDC therapy. Sulfamethoxypyrazine and Pyrimethamine are both excreted into maternal

milk. Artesunate does not appear in breast milk of lactating mothers, and its metabolite Dihydroartemisinin is present in insignificant amounts.

4.7 Effects on ability to drive and to use machines

No reactions are noted to date.

4.8 Undesirable effects

The disease itself is characterised by unpleasant symptoms which should not be confused with drug side effects. Undesirable effects from Artesunate are generally rare at the therapeutic dose. In very rare cases, slight changes in haematologic values have been seen, including a reduction in reticulocyte number and a slight increase in transaminases, generally without noticeable clinical manifestations. In rare cases, slight transient reduction in sinus heart rate has been observed, without affecting the QTc interval. Abdominal cramps and mild diarrhoea have been reported at elevated doses, transient in nature.

Side effects with Sulfamethoxypyrazine are extremely rare; Stevens-Johnson syndrome or Lyell syndrome have never been described but may theoretically occur. Crystalluria does not occur due to the excellent solubility of the compound and its acetylated metabolite.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

4.9 Overdose

The recommended dose should not be exceeded. In case of accidental overdosage, symptomatic treatment in a specialised centre is required.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutical class: Antimalarial drug. Artesunate is a very active derivative of the Artemisinins, a class of antimalarial drugs derived from Artemisinin (extracted from Artemisia annua); Artesunate is prepared semi-synthetically. Sulfamethoxypyrazine is a long-acting sulphonamide acting as a folic acid biosynthesis inhibitor. Pyrimethamine is also a folic acid biosynthesis antagonist (reductase inhibitor).

Co-Arinate FDC is an Artemisinin-based Combination Therapy (ACT) containing three medicaments active against malaria parasites. Artesunate kills parasites very fast and potentiates the effects of Sulfamethoxypyrazine and Pyrimethamine, which have a long elimination half-life. This combination permits a shorter treatment duration, improving compliance, and significantly reduces the theoretical risk of drug resistance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

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6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

2 Years.

6.4 Special precautions for storage

Tablets should be kept dry, protected from light and stored at a temperature below 30°C in their original packaging. Do not exceed the expiry date printed on the package (EXP). Keep out of reach and sight of children.

6.5 Nature and contents of container

Box containing 1 blister of 3 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

ENERGIA PHARMA LIMITED

8. MARKETING AUTHORISATION NUMBER(S)

H2008/19221/738/R1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26-06-2026

10. DATE OF REVISION OF THE TEXT

22-08-2026