

Prescribing Information

Please consult the Summary of Product Characteristics (SPC) before prescribing.

Malarone Tablets (250mg atovaquone/100mg proguanil hydrochloride) and Malarone Paediatric Tablets (62.5mg atovaquone/25mg proguanil hydrochloride).

Uses: *Malarone*: Prophylaxis of *Plasmodium falciparum* malaria and treatment of acute, uncomplicated *P. falciparum* malaria, especially where pathogen may be resistant to one or more other anti-malarial agents.

Malarone Paediatric: Prophylaxis of *P. falciparum* malaria in individuals weighing 11-40 kg. Treatment of acute, uncomplicated, *P. falciparum* malaria (children \geq 5kg and $<$ 11kg). **Dosage:** Take once daily at the same time each day with food or a milky drink. *Malarone Paediatric* tablets: crush and mix with food or a milky drink if necessary. **Prophylaxis:** Start 24-48 hours prior to entering a malaria-endemic area, continue during the period of the stay and for 7 days after leaving the area.

Adults and children $>$ 40kg: 1 *Malarone* (250/100mg) tablet daily; 31-40 kg: 3 *Malarone Paediatric* (62.5/25mg) tablets daily; 21-30 kg: 2 *Malarone Paediatric* tablets daily; 11-20 kg: 1 *Malarone Paediatric* tablet daily.

Treatment: Take as a single dose for three consecutive days. Adults and children $>$ 40kg: 4 *Malarone* (250/100mg) tablets; 31-40kg: 3 *Malarone* tablets; 21-30kg: 2 *Malarone* tablets; 11-20kg: 1 *Malarone* tablet. Children 9-10kg: 3 *Malarone Paediatric* (62.5/25 mg) tablets; 5-8kg: 2 *Malarone Paediatric* tablets.

Contraindications: Hypersensitivity to any ingredient; creatinine clearance $<$ 30mL/min if for prophylaxis.

Precautions: Repeat dose if vomiting within 1 hour of dosing. **Treatment:** Consider alternative therapy in acute malaria presenting with diarrhoea or vomiting; creatinine clearance $<$ 30mL/min with acute *P. falciparum* malaria. Use additional agents to treat *P. vivax* or *P. ovale*. In the event of recrudescence infections due to *P. falciparum* after treatment with *Malarone*, or failure of chemoprophylaxis with *Malarone* paediatric tablets, patients should be treated with a different blood schizonticide as such events can reflect a resistance of the parasite. May cause dizziness; caution if affected. Occasional severe allergic reactions (including anaphylaxis); discontinue promptly and initiate appropriate treatment. Parasitaemia should be closely

monitored in patients on concurrent tetracycline. Caution advised when initiating and withdrawing prophylaxis/treatment with *Malarone* in patients on continuous treatment with warfarin and other coumarin based anticoagulants. Concomitant administration of *Malarone* and efavirenz or boosted protease inhibitors should be avoided whenever possible. Co-administration with rifampicin and rifabutin is not recommended. Concomitant use of metoclopramide is not recommended and another antiemetic should be given instead. Increased etoposide plasma concentration in children taking atovaquone and caution advised with concomitant use. Tetracycline reduces atovaquone levels. **Pregnancy & Lactation:** **Pregnancy:** The potential risk during pregnancy is unknown. So the use of *Malarone* tablets should only be considered if the expected benefit to mother outweighs any potential risk to foetus. For women of childbearing age receiving folate supplements to prevent neural tube birth defects, such supplements should be continued while taking *Malarone* paediatric tablets. **Lactation:** Should not be taken. **Adverse reactions:** See SPC for full details. **Very common:** headache, GI symptoms. **Common:** anaemia, neutropenia, allergic reactions, hyponatraemia, anorexia, abnormal dreams, depression, insomnia, dizziness, elevated liver enzymes, pruritus, rash, fever, cough. **Serious:** Palpitations, hallucinations, pancytopenia, angioedema, anaphylaxis, vasculitis, neuropsychiatric disorders, seizure, Stevens-Johnson syndrome, skin exfoliation, photosensitivity reactions. **Legal category:** POM. **Presentation and basic NHS cost:** *Malarone* Tablets. 12, £25.21. *Malarone Paediatric* Tablets. 12, £6.26. **MA numbers:** PL 10949/0258, PL 10949/0363. **MA holder:** Glaxo Wellcome UK Ltd trading as GlaxoSmithKline UK, 980 Great West Road, Brentford, Middlesex, TW8 9GS. For further information, please contact the GSK Customer Contact Centre: customercontactuk@gsk.com, freephone 0800 221 441. *Malarone* is a registered trademark of the GlaxoSmithKline group of companies. **Date of preparation:** December 2019 **Ref:** PI-2431 (V3.0).

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellowcard in the Google Play or Apple App store.

Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.