

**Maloff
protect**

atovaquone/proguanil
hydrochloride



VISIT THE WEBSITE

Risk Management Materials (RMMs) are provided by Glenmark Pharma and are a mandatory condition of the Marketing Authorisation to support the recommendation, sale or supply of Maloff Protect -these are available via the EMC website and maloff@glenmarkpharma.com

- Chemoprophylaxis should be recommended in combination with bite prevention and travellers should have a full travel consultation, and advice should include an overall risk assessment-based package, not just malaria prophylaxis
- Choice of anti-malarial should be based on various factors, customer or drug related (e.g. location and duration of travel, potential for drug resistance, traveller age, pregnancy, presence of contraindications)

Essential Information. Name of product Maloff Protect 250mg/100mg tablets **List of actives** atovaquone, proguanil **PL number** PL 25258/0166 **Name and address of PL holder** Glenmark Pharmaceuticals Europe Limited, Laxmi House, 2 B Draycott Avenue, Kenton, Middlesex, HA3 0BU. **Supply classification (P/GSL)** P **Indication(s)** Chemoprophylaxis of *Plasmodium falciparum* (*P. Falciparum*) malaria in adults. Check official guidelines (e.g. World Health Organisation (WHO) and public health authorities' guidelines) before dispensing. **Contraindications, precautions, side effects** Contraindications: hypersensitivity to atovaquone, proguanil or excipients, renal disease, hepatic impairment, children and adolescents. Precautions: if vomiting occurs within one hour of dosing repeat dose. If allergic reaction develops, discontinue use promptly and seek medical treatment. Refer the following patients to a doctor or other qualified prescriber: those taking etoposide, rifampicin, rifabutin, metoclopramide, warfarin and other anticoagulants, tetracycline, indinavir, efavirenz, zidovudine, boosted protease inhibitors, those with a history of depression or seizures, those with TB, patients who are pregnant, planning to become pregnant or those breast feeding. Safety and effectiveness has not been established in patients <40kg.

Remind travellers of the need for a full travel consultation. The most common side effects are headache, abdominal pain and diarrhoea. Other important reactions reported are severe allergic reactions, pancytopenia in patients with severe renal impairment, severe skin reactions, seizure, hallucinations, liver inflammation, depression. **Dosage and method used** One tablet daily with food or a milky drink at the same time each day. Commence 1-2 days prior to entering malaria-endemic area, continue for the duration of the stay plus seven days after leaving the area. The maximum duration of travel for which Maloff Protect can be supplied without prescription is 12 weeks (93 tablets). For longer durations of travel, advice should be sought from a doctor or other qualified prescriber. **Cost** RRP (excluding VAT): 24 Tablet Pack = £39.00, 36 Tablet Pack = £56.16 **Date of EI creation** June 2017

Adverse events should be reported.

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to Glenmark Pharmaceuticals Ltd on 01923 202950 or medical_information@glenmarkpharma.com

References: 1. Maloff Protect Summary of Product Characteristics. 2. British National Formulary. Prophylaxis against malaria. <https://www.evidence.nhs.uk/formulary/bnf/current/5-infections/54-antiprotozoal-drugs/541-antimalarials/prophylaxis-against-malaria>. Accessed April 2017.