

Maloff EI (Essential Information) for PQPS

Long form

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 <i>Plasmodium falciparum</i> (<i>P. Falciparum</i>) malaria in adults. Check official guidelines (e.g. World Health Organisation (WHO) and public health authorities' guidelines) before dispensing.
	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.
Adverse Event Reporting	Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk .
Cost**	RRP (excluding VAT): 24 Tablet Pack = £39.00, 36 Tablet Pack = £58.50
Date of EI creation	April 2022