

PRESCRIBING INFORMATION

Diloxanide 500mg tablets (diloxanide furoate)

Presentation: Each tablet contains 500mg diloxanide furoate.

Indication: For the treatment of acute and chronic intestinal amoebiasis.

Dosage and administration: For oral use.

Adults: One 500mg tablet three times daily for ten days.

Elderly: There is no need for dosage reduction in the elderly.

Children: 20 mg/kg bodyweight daily in divided doses for ten days. Diloxanide is not suitable for use in children weighing less than 25 kg.

Contraindications: Hypersensitivity to diloxanide furoate.

Precautions and warnings: Keep all medicines out of the reach of children.

Interactions: No clinically significant drug interactions known.

Pregnancy and lactation: Contraindicated in pregnancy and lactation.

Undesirable effects: Vomiting, flatulence, pruritus and urticaria may occur.

(Please refer to the Summary of Product Characteristics for detailed information)

Overdose: Diloxanide tablets are unlikely to constitute a hazard in overdosage. In severe overdosage, early gastric lavage is recommended. There is no specific antidote. Treatment should be symptomatic and supportive.

Legal category: POM

Basic NHS cost: £93.50 for 30 tablets.

Marketing Authorisation Number: PL 20072/0225

Marketing Authorisation Holder: Amdipharm Mercury Company Limited (AMCo), 1st Floor, Capital House, 85 King William Street, London, EC4N 7BL.

Date of preparation: April 2014

Adverse events should be reported to the local regulatory authority.

Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard**
Adverse events should also be reported to **Amdipharm Mercury Medical Information**
at **08700 70 30 33** or via e-mail to **medicalinformation@amcolimited.com**