04.04.2005
Circular No. P09/2005

Dear Healthcare Professional,

Re: Quinine and the risk of thrombocytopenia

Following a review by the Medicines Authority regarding the current licensing status of quinine and its use in nocturnal leg cramps, the following information is being sent for your perusal.

Currently there is one quinine product authorised for marketing in Malta (MA144/02/701). The Summary of Product Characterisitcs (SmPC) of this product lists in section 4.1 the treatment of falciparum malaria and the prevention of nocturnal leg cramps. The current SmPC also lists thrombocytopenia in section 4.8 as an undesirable effect. Furthermore, the following immunological effects are also listed: agranulocytosis, thrombocytopenic purpura, intravascular coagulation and haemolysis.

The Medicines Authority has to date received no local Adverse Drug Reaction (ADR) reports associating quinine with thrombocytopenia. Since the risk of thrombocytopenia is covered in the SmPC of the product licensed locally, the Medicines Authority concludes that the indication for prevention of nocturnal leg cramps does not need to be withdrawn, and advises doctors to carry out a benefit vs. risk assessment when prescribing quinine in individual patients, bearing in mind that cases of thrombocytopenia might be associated with the use of quinine.

The Medicines Authority therefore reminds all Healthcare Professionals about the importance of reporting any suspected serious or unexpected ADRs to the Medicines Authority, as outlined in article 4(b) of the Pharmacovigilance Regulations, 2004 (LN 22 of 2004) which can be downloaded from the Medicines Authority's website www.health.gov.mt/mru

Medicines Authority
198, Rue D'Argens, Gzira, GZR 03 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 email: info.mru@gov.mt