

**Important New Dispensing Information:  
Issuance of a Medication Guide for LARIAM®  
(mefloquine hydrochloride) Tablets to Prevent Malaria**



Pharmaceuticals

September 2003

Dear Health Care Professional:

Roche Laboratories wishes to inform you of the introduction of the Lariam Medication Guide (MedGuide), which must be provided to anyone who is given Lariam for the prophylaxis of malaria. The Lariam MedGuide was developed in collaboration with the Food and Drug Administration (FDA) to help travelers better understand the risks of malaria, the risks and benefits associated with taking Lariam to prevent malaria, and the rare but potentially serious psychiatric adverse events associated with use of the drug.

Lariam is indicated for the treatment of mild to moderate acute malaria caused by mefloquine-susceptible strains of *Plasmodium falciparum* (both chloroquine-susceptible and resistant strains) or by *Plasmodium vivax*. Lariam is also indicated for the prophylaxis of *P. falciparum* and *P. vivax* malaria infections, including prophylaxis of chloroquine-resistant strains of *P. falciparum*. The Lariam MedGuide is intended only for travelers who are taking Lariam to prevent malaria. The information in the MedGuide may not apply to patients who are sick with malaria and who are taking Lariam to treat malaria.

The Lariam MedGuide uses consumer language to summarize information in the professional package insert, including the approved indication and major adverse events. To help ensure that travelers are informed of this important safety information, it is required that a Lariam MedGuide be presented to the traveler each time that Lariam is dispensed.

Roche Laboratories is committed to providing you with the most current product information for Lariam. You can assist us in monitoring the safety of Lariam by reporting adverse reactions to Roche Laboratories at 1-800-526-6367 or to the FDA MedWatch program by telephone at 1-800-332-1088, by FAX at 1-800-332-0178, via [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or by mail to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20857.

If you have any questions about the Lariam MedGuide or want additional information regarding Lariam please contact the Roche Pharmaceuticals Service Center at 1-800-526-6367.

If you wish to request additional copies of the Lariam MedGuide please call 1-800-710-1381.

Sincerely,

A handwritten signature in black ink, appearing to read "Lars Birgerson".

Lars Birgerson, MD  
Vice President, Medical Affairs

Enclosures:  
Lariam Tablets Medication Guide  
Lariam Tablets Complete Product Information

16-004-047-015-0903