

DEPARTMENT OF THE ARMY

OFFICE OF THE SURGEON GENERAL 5109 LEESBURG PIKE FALLS CHURCH, VA 22041-3258

DASG-PPM-NC

0 3 OCT 2002

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Updated Health Care Provider Information on Use of Mefloquine Hydrochloride (Lariam®) for Malaria Prophylaxis

1. References:

- a. US Army Center for Health Promotion and Preventive Medicine, Malaria and Mefloquine (with links). http://chppm-www.apgea.army.mil/malariaandMefloquine/
- b. Mefloquine (Lariam®) package insert. http://www.rocheusa.com/products/lariam/pi.html
- c. DOD Medical Materiel Quality Control (MMQC) Message 161253Z Sep02, SUBJ: MMQC-02-1302, Important Label Changes/Lariam (Mefloquine Hydrochloride)/Updated Information Bulletin.
 - d. AR 40-3, Medical, Dental, and Veterinary Care, 30 July 1999.
- 2. Falciparum malaria remains one of the deadliest infectious disease threats to soldiers deployed around the world. Use of appropriate prophylactic medication, in addition to the DOD repellent system and barriers such as bed nets, provides optimal force health protection against this threat.
- 3. In many areas of the world where chloroquine-resistant malaria is found, especially Africa and South America, mefloquine (Lariam®) 250 mg provides safe and effective prophylaxis against susceptible strains of falciparum malaria, with the advantage of a weekly dosing regimen.
- 4. Malaria prophylaxis with mefloquine is well tolerated by most persons. In the more than 12 years since mefloquine was licensed for use in the United States by the US Food and Drug Administration, mefloquine has been safely used to protect many thousands of persons against malaria, and remains a critical element of malaria prevention for the Army.

DASG-PPM-NC

SUBJECT: Updated Health Care Provider Information on Use of Mefloquine Hydrochloride (Lariam®) for Malaria Prophylaxis

- 5. It is critically important that all Army health care providers be familiar with the proper use, contraindications, warnings, and precautions for prescribing mefloquine, especially with respect to the recent changes in the manufacturer's labeling information. These changes, summarized below and in a related MMQC message (para. 1.c.), focus primarily on neurobehavioral effects and do not represent the full clinical profile of this medication. Providers must refer to the package insert (para. 1.b.) for complete prescribing information.
- a. Contraindications. Use of Lariam® is contraindicated in patients with known hypersensitivity to mefloquine or related compounds (e.g., quinine and quinidine). Lariam® should not be prescribed for prophylaxis in patients with active depression or a recent history of depression; generalized anxiety disorder, psychosis or schizophrenia or other major psychiatric disorders; or with a history of seizure disorder or epilepsy.
- b. Warnings and Precautions. When used for prophylaxis, mefloquine may cause psychiatric symptoms at a rate of one per 2,000-13,000 persons. These symptoms include anxiety, paranoia, depression, hallucinations and psychotic behavior. Rarely, these symptoms have been reported to continue after mefloquine has been stopped. Rare cases of suicidal ideation and suicide have been reported although no relationship to drug administration has been confirmed.
- c. Patient information. Patients should be advised that if they experience psychiatric symptoms such as excessive acute anxiety, depression, restlessness or confusion, these may be considered prodromal to a more serious event related to mefloquine. In these cases, the drug must be discontinued and an alternative medication should be substituted.
- 6. Adverse event reporting. IAW AR 40-3 (ref 1.d), [para. 11-6d(9)], all known or suspected adverse events related to the administration of mefloquine will be reported to the appropriate Pharmacy and Therapeutics Committee for further review and consideration to forward to the US Food and Drug Administration.
- 7. The point of contact for this information is COL Robert DeFraites, DSN 761-3146.

JAMES B. PEAKE, M.D. Lieutenant General

The Surgeon General

DASG-PPM-NC

SUBJECT: Updated Health Care Provider Information on Use of Mefloquine Hydrochloride (Lariam®) for Malaria Prophylaxis

DISTRIBUTION:

COMMANDER, EUROPEAN REGIONAL MEDICAL COMMAND

COMMANDER, GREAT PLAINS REGIONAL MEDICAL COMMAND

COMMANDER, NORTH ATLANTIC REGIONAL MEDICAL COMMAND

COMMANDER, PACIFIC REGIONAL MEDICAL COMMAND

COMMANDER, SOUTHEAST REGIONAL MEDICAL COMMAND

COMMANDER, WESTERN REGIONAL MEDICAL COMMAND

COMMANDER, US ARMY DENTAL COMMAND

COMMANDER, US ARMY VETERINARY COMMAND

COMMANDER, CENTER FOR HEALTH PROMOTION AND PREVENTIVE MEDICINE

COMMANDER, AMEDD CENTER AND SCHOOL

COMMANDER, MEDICAL RESEARCH AND MATERIEL COMMAND

COMMANDER, 18TH MEDICAL COMMAND

CHIEF, ARMY RESERVE, ATTN: DAAR-MA

CHIEF, ARMY NATIONAL GUARD BUREAU, ATTN: NGB-ARS

HQ, US ARMY FORCES COMMAND, ATTN: AFMD

HQ, US ARMY TRAINING AND DOCTRINE COMMAND, ATTN: ATMD

HQ, US ARMY MATERIEL COMMAND, ATTN: AMMD

HQ, US ARMY SPECIAL OPERATIONS COMMAND, ATTN: AOMD

HQ, 3RD US ARMY, ATTN: SURGEON

HQ, US ARMY PACIFIC, ATTN: SURGEON

HQ, US ARMY SOUTH, ATTN: SURGEON

HQ, US ARMY EUROPE, ATTN: SURGEON