NOVARTIS

STAT-GRAM®

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Distribution Changes for Lamprene®

Dear Doctor:

As a prescriber of Lamprene® (clofazimine), you may already be aware that Novartis has been supporting the efforts of the World Health Organization (WHO) to eliminate leprosy as a public health problem since the year 2000. As part of this commitment, Novartis provides Lamprene free of charge to all leprosy patients around the world.

In the United States, our partner in this effort is the National Hansen's Disease Programs (NHDP), a unit of the US Department of Health and Human Services, based in Baton Rouge, Louisiana.

Commercial Distribution of Clofazimine Ceased

As of November 1, 2004, Novartis Pharmaceuticals Corporation ceased commercial distribution of clofazimine in the United States. Instead, clofazimine remains available for the treatment of leprosy under an IND (Investigational New Drug) application held by NHDP.

For Leprosy Therapy

To receive clofazimine for use in the treatment of leprosy, you must be enrolled as an investigator under the IND held by NHDP. To enroll as an investigator, contact Ms. Renee Painter at the address below. Ms. Painter will provide you with the necessary paperwork for this process. As an investigator, you will be required to provide, on an annual basis, safety information about the use of clofazimine in your patients.

Renee Painter
Administrative Officer
Laboratory Research Branch
RPAINTI@LSU.EDU
Skip Bertman Drive
Baton Rouge LA 70803
Phone: (225) 578-9861
Fax: (225) 578-9856

For Non-Leprosy Therapy

The "off-label" use of Lamprene® (clofazimine) is discouraged by WHO and Novartis because it is a first-line drug for the treatment of leprosy, and its off-label use must be guarded against to prevent resistance. Moreover, the safety and efficacy of clofazimine outside the FDA-approved indication for the treatment of lepromatous leprosy have not been established in well-designed, controlled, randomized clinical trials. Consequently, Novartis does not recommend the use of clofazimine beyond the FDA-approved indication.

If, however, a physician believes that no comparable or satisfactory drug or therapy is available to the patient, he/she may submit a request for a single patient IND to the FDA. If the FDA approves such a request, clofazimine will be made available.

All requests for use of clofazimine in medical conditions other than leprosy must be directed to:

Division of Special Pathogen and Immunologic Drug Products (HFD-590)
Center for Drug Evaluation and Research
Food and Drug Administration

(301) 796-1600

Upon approval of the single patient IND, the FDA will request NHDP to distribute clofazimine directly to the prescriber.

If you have any additional questions about this process, please contact Novartis at 1-888-NOW-NOVA between 9:00 AM and 5:00 PM Eastern Time, Monday through Friday.

Sincerely,

SR Cunningham

Stephen Cunningham, MD
Vice President and Head
US Clinical Development & Medical Affairs
Novartis Pharmaceuticals Corporation

Please see complete prescribing information for Lamprene enclosed.