

ELECTRONIC MAIL MESSAGE

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Subject: PROPULSID (CISAPRIDE) limited-access program

Janssen Pharmaceutica Press Release

LIMITED-ACCESS PROGRAM ANNOUNCED IN UNITED STATES TO ENSURE APPROPRIATE USE OF PROPULSID (CISAPRIDE)

Product No Longer To Be Promoted in United States

March 23, 2000 - Titusville, NJ - A limited-access program will be initiated for Propulsid (cisapride) tablets and suspension, and the product will no longer be marketed in the United States, it was announced today by Janssen Pharmaceutica of Titusville, NJ. Propulsid is a prescription treatment approved by the Food and Drug Administration (FDA) for symptomatic treatment of adults with nighttime heartburn due gastroesophageal reflux disease (GERD).

Under the new program, Propulsid will remain available to appropriate patients for whom other therapies are not effective and who meet clearly defined eligibility criteria. These criteria are being established in close collaboration with the FDA.

Information on the limited-access program will be sent to physicians across the country in April, and enrollment will begin May 1. However, to assure that the medication is available to patients during the transition, distribution will continue until July 14, and the product will remain in pharmacies until mid August. Patients who have current prescriptions for Propulsid are advised to speak with their doctors.

Since the U.S. approval of Propulsid in 1993, there have been a number of serious cardiovascular side effects in individuals who also were taking certain contraindicated medications or who had specific underlying health conditions. In an effort to ensure that the drug was being prescribed safely and appropriately, labeling changes were initiated over the past several years, making the prescribing information as detailed and specific as possible.

Despite these warnings, some inappropriate use has continued in the United States. Janssen and the FDA now believe the best way to address this situation is to limit access to the medication, while ensuring that appropriate patients who have exhausted other treatment options can still benefit from it. Propulsid remains safe and effective for the vast

...safety of patients when used according to the approved prescribing
...information.

Details regarding how the limited-access program will work -- including
eligibility criteria and the application process -- are currently being
developed by Janssen in consultation with the FDA. In the meantime,
consumers and health-care professionals with questions may call
1-800-JANSSEN from 9 a.m. to 5 p.m. Monday to Friday, Eastern Standard
Time.