JANSSEN PHARMACEUTICA PRODUCTS, L.P.

IMPORTANT SAFETY INFORMATION

May, 2001

Dear Health Care Professional,

Janssen Pharmaceutica Products, L.P. and Ortho Biotech Products, L.P. would like to inform you about revised labeling for SPORANOX® (itraconazole) Capsules, SPORANOX® (itraconazole) Injection and SPORANOX® (itraconazole) Oral Solution. The revision to the labeling came about as a result of the company's ongoing research, monitoring and evaluation of our marketed products. Clinicians are advised to carefully review the pertinent sections of the prescribing information. A package insert for each formulation has been enclosed for your review.

SPORANOX® Capsules should not be administered to treat onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF. Rare cases of CHF and pulmonary edema have been reported in the postmarketing period in patients treated with SPORANOX® Capsules. These patients were being treated for onychomycosis and/or systemic fungal infection. If signs or symptoms of congestive heart failure occur during administration of SPORANOX® Capsules, discontinue administration.

If signs or symptoms of congestive heart failure occur during administration of SPORANOX® Injection or Oral Solution, continued SPORANOX® use should be reassessed.

In a canine study, intravenous itraconazole exerted a dose-related negative inotropic effect on the heart. In a healthy human study of intravenous itraconazole, transient asymptomatic decreases in left ventricular ejection fraction were observed; these resolved before the next infusion. Negative inotropic effects may result in manifestation or worsening of signs and symptoms of congestive heart failure. Appropriate information on this negative inotropic effect is added to the Clinical Pharmacology, Contraindications (Capsules only), Warnings, Precautions and Adverse Reactions sections of the attached labeling for each formulation of SPORANOX®.

Other revisions to the labeling include a contraindication for use of SPORANOX® with **dofetilide (Tikosyn™)** a Class III antiarrhythmic, a precaution for use with **erythromycin**, and modifications of the calcium channel blocker drug interaction statement.

For a complete discussion of the changes, please refer to the Boxed Warning, Clinical Pharmacology: Special Populations, Indications, Contraindications, Warnings, Precautions: Information for Patients, Drug Interactions, Adverse Reactions: Post-Marketing Experience, Dosage and Administration, and How Supplied sections of the enclosed Package Insert for each dosage form.

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POST OFFICE BOX 200
TITUSVILLE, NEW JERSEY 08560-0200
(609) 730-2000

us.janssen.com

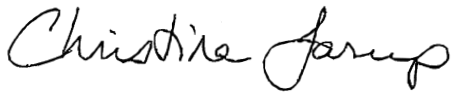
SPORANOX® (itraconazole) Injection and SPORANOX® (itraconazole) Oral Solution are distributed by Ortho Biotech Products, L.P. SPORANOX® (itraconazole) Capsules are distributed by Janssen Pharmaceutica Products, L.P.

Janssen Pharmaceutica and Ortho Biotech are committed to providing you with the most current prescribing information for the management of your patients receiving SPORANOX®. You can further our understanding of adverse events by reporting all cases to Janssen or Ortho Biotech at the contact numbers below or to the FDA MedWatch Program by phone 1-800-FDA-1088, by fax 1-800-FDA-0178, by mail (using postage-paid form) MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or via www.fda.gov/medwatch.

Please refer to the enclosed revised full prescribing information, including Boxed Warning. The prescribing information for SPORANOX® Capsules is also available at http://us.janssen.com. Prescribing information for SPORANOX® Injection and SPORANOX® Oral Solution can be viewed at www.sporanoxiv.com. For additional medical information, please call between 9 AM and 4:30 PM E.D.T. Monday through Friday:

SPORANOX® Capsules:	1-800-JANSSEN (526-7736)
SPORANOX® Oral Solution or SPORANOX® Injection:	1-800-325-7504, Prompt #2

Sincerely,



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