

IMPORTANT NEW SAFETY INFORMATION

May 9 , 2001

Dear Health Care Professional,

Janssen-Ortho Inc. would like to inform you of revised Prescribing Information for SPORANOX* (itraconazole) Capsules and Oral Solution. This revision 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 Contraindications (Capsules only), Warnings, Precautions and Adverse Reactions sections of the revised Prescribing Information. A highlighted copy of the Prescribing Information for each dosage form has been enclosed for your review. Please insert this information in your copy of the CPS and use when prescribing and dispensing SPORANOX.

Rare cases of congestive heart failure (CHF) and pulmonary edema have been reported in the post-marketing period in patients treated with SPORANOX. The majority of these patients were being treated for onychomycosis and/or systemic fungal infections.

SPORANOX Capsules

SPORANOX Capsules should not be administered to treat onychomycosis or dermatomycoses in patients with evidence of ventricular dysfunction, such as CHF or a history of CHF. If signs or symptoms of CHF occur during administration of SPORANOX Capsules, discontinue administration.

SPORANOX Oral Solution

If signs or symptoms of CHF occur during administration of SPORANOX Oral Solution, discontinue administration.

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 CHF. Appropriate information on this negative inotropic effect has been added to the Contraindications (Capsules only), Warnings, Precautions and Adverse Reactions

sections of the attached Prescribing Information for each dosage form of SPORANOX.

Other revisions to the Prescribing Information include a precaution for use with **erythromycin**, and modification of the **calcium channel blocker** drug interaction statement.

Janssen-Ortho Inc. is committed to providing you with the most current product information available for the management of your patients receiving SPORANOX. SPORANOX remains safe and effective when used according to the approved Prescribing Information. Healthcare providers are reminded of the importance of carefully reviewing the revised Prescribing Information when prescribing SPORANOX. In addition, you can further our understanding of adverse events by reporting all cases to Janssen-Ortho Inc. at 1-800-567-3331 and to Health Canada following the instructions provided in Appendix 7A, p. A11 of the 2001 CPS.

Please refer to the enclosed revised Prescribing Information for SPORANOX Capsules and Oral Solution. For additional information concerning SPORANOX, please contact our Medical Information Department at 1-800-567-3331 from 9 a.m. to 5 p.m. Monday to Friday, Eastern Standard Time or access the Janssen-Ortho Inc. Web site at <http://www.janssen-ortho.com>. On the Web site, you will find a copy of this letter, the revised Prescribing Information for SPORANOX Capsules and Oral Solution, and a press release.

Sincerely,

A handwritten signature in black ink, appearing to read 'Wendy Arnott', written in a cursive style.

Wendy Arnott, Pharm. D.
Vice President Medical, Regulatory, Quality, Linguistics