

Presutti

Presutti Laboratories, Inc.
1585 Winnatka Circle
Rolling Meadows, IL 60008

Tel: 888-405-7800
Fax: 847-788-9192
www.presuttifabs.com

September 13, 2004

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Dear Dr. []

Presutti Laboratories is pleased to introduce our new prescription product, **Tindamax™** (tinidazole tablets). Tindamax is the new replacement for metronidazole offering excellent efficacy with minimal side effects. The initial indications for Tindamax are trichomoniasis, giardiasis, intestinal amebiasis and amebic liver abscess. Additional indications are under development. Tindamax is available in 500mg and 250mg film-coated tablets.

Tindamax is a second generation 5-nitroimidazole, in the same chemical class as metronidazole but with the following key benefits:

- Over 90% efficacy with a single 2g dose in the treatment of trichomoniasis and giardiasis.
- A shorter dosing regimen than metronidazole in treating both giardiasis and amebiasis.
- Demonstrated utility in metronidazole resistant trichomoniasis and giardiasis at higher doses.
- Low incidence of GI side effects. The pooled data from seven trichomoniasis clinical trials showed that tinidazole produced approximately half the incidence of GI side effects as a comparable dose of metronidazole.
- Longer half-life than metronidazole (12-14 hours for Tindamax vs. 6-8 hours for metronidazole). Therapeutic concentrations of Tindamax are maintained for 48 hours.
- Higher tissue levels than metronidazole in both female and male reproductive tissues.
- Greater *in-vitro* potency than metronidazole against most protozoa (including metronidazole resistant *T. vaginalis*) and anaerobic bacteria.

Tindamax is recommended as a drug of choice for the treatment of trichomoniasis by the CDC, Division of Parasitic Diseases, The Medical Letter, The World Health Organization (WHO) and The Cochrane Review. The Medical Letter also recommends Tindamax as a drug of choice for the treatment of giardiasis and amebiasis.

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The dosing schedule for **Tindamax™** (tinidazole tablets) is as follows:

Tindamax Adult Dosing Schedule	
Trichomoniasis	2g single dose
Giardiasis	2g single dose
Intestinal Amebiasis	2g QD x 3 days
Amebic Liver Abscess	2g QD x 3-5 days

Tindamax should be dosed with food and the patient should be instructed not to consume alcohol for 72 hours after taking Tindamax. Tindamax, like metronidazole, is contraindicated in the first trimester of pregnancy. Tindamax is available in strengths of 500mg and 250mg tablets.

Enclosed is a file card which offers more information regarding Tindamax including the full prescribing information. Tindamax is now available at most pharmacies.

To obtain samples of Tindamax via UPS, please fill out and return the enclosed business reply card (BRC). One 500mg sample bottle contains 4 tablets which is a complete course of therapy for giardiasis (2g dose). One 250mg sample bottle contains 8 tablets. Please confirm that the address on the BRC is where you want the samples delivered. We are unable to deliver samples to a PO Box and a signature must be obtained upon delivery. It is also important to provide your state license number on the BRC.

If you have any questions, please contact us at 888-405-7800. Thank you for your consideration of Tindamax.

Sincerely,



John E. Presotti
President

Enclosures

Selected safety information

Tindamax has not been studied in pregnant women. Tindamax crosses the placental barrier and is contraindicated during the first trimester of pregnancy. Although not reported for tinidazole, another member of the nitroimidazole class (metronidazole) has been shown to be a carcinogen in rodents. Unnecessary use of this drug should be avoided. The appearance of abnormal neurologic signs demands prompt discontinuance of therapy. Use with caution in patients with blood dyscrasia. Administer usual recommended dose cautiously for patients with hepatic dysfunction.