



## Therapeutic Class Review<sup>SM</sup>

### Anti-infectives - Tinidazole (Tindamax<sup>TM</sup>)

May 2005

#### New Product for Review

tinidazole (Tindamax) [Presutti]

#### Dossier Provided by Manufacturer: yes

#### Quality of Dossier: 2

1. Low quality (dossier w/missing components)
2. Medium quality (all components, except pharmacoeconomic model)
3. High quality (all components, well done)

#### Issues

- Is there sufficient scientific evidence to support a clinical value of tinidazole (Tindamax<sup>TM</sup>) over other formulary alternatives?

#### Executive Summary

- Tinidazole (Tindamax) is a synthetic antiprotozoal and antibacterial agent similar to metronidazole. It has been used in Asian, African, and European countries for over 30 years to treat amebiasis, amebic liver abscess, giardiasis and trichomoniasis.
- Historical data from studies conducted during the 1970s and 1980s show that tinidazole (Tindamax) is superior to metronidazole for the treatment of amebiasis, amebic liver abscess and giardiasis, and both drugs were equally efficacious in treating trichomoniasis.
- There is no evidence support that tinidazole (Tindamax) is better than metronidazole in overall safety.
- There are no randomized controlled trials to show efficacy and safety of Tindamax in treating trichomoniasis, giardiasis, amebiasis, and amebic liver abscess in U.S. patients.

## **Decision**

Maintain tinidazole (Tindamax) as non-formulary/non-preferred product because the likely use for tinidazole (Tindamax) will be primarily for the treatment of trichomoniasis, a condition for which tinidazole (Tindamax) has not shown any better efficacy than metronidazole.

## Products

Drug Product	Date of FDA Approval	FDA Approved Indication(s)	Dose Route	Potential Off-Label Use(s)
tinidazole (Tindamax) 250 mg and 500 mg tablets	May 17, 2004	Treatment of <b>trichomoniasis</b> caused by <i>T. vaginalis</i> in both female and male patients. Treatment of <b>giardiasis</b> caused by <i>G. duodenalis</i> (also termed <i>G. lamblia</i> ), and treatment of <b>intestinal amebiasis</b> and <b>amebic liver abscess</b> caused by <i>E. histolytica</i> in both adults and pediatric patients older than three years of age.	Oral	Eradication of <i>Helicobacter pylori</i> . <sup>1,2</sup> Treatment of pelvic inflammatory disease. <sup>3</sup> management of infectious diabetic foot ulcer. <sup>4</sup>
metronidazole metronidazole	July 18, 1963	Symptomatic/asymptomatic <b>trichomoniasis</b> and asymptomatic consorts. <b>Amebiasis.</b> <b>Anaerobic Bacterial Infections.</b>  Intra-abdominal including peritonitis, intra-abdominal abscess, and liver abscess, skin and skin structure infections, gynecological infections including endometritis, endomyometritis, tubo-ovarian abscess, and postsurgical vaginal cuff infection, bacterial sepsis, bone and joint infections (adjunctive therapy), central nervous system infections, including meningitis and brain abscess, lower respiratory tract infection including pneumonia, empyema, and lung abscess, and endocarditis. [The causative organisms for these infections must include <i>Bacteroides</i> species ( <i>B. fragilis</i> group ( <i>B. fragilis</i> , <i>B. distasonis</i> , <i>B. ovatus</i> , <i>B. thetaiotaomicron</i> , <i>B. vulgatus</i> ), <i>Clostridium</i> species, <i>Eubacterium</i> species, <i>Peptococcus niger</i> , and <i>Peptostreptococcus</i> species].	Oral, topical and intravenous	

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