TINIDAZOLE TABLETS

HILOGLY OF PRESCRIBING INFORMATION

Tinidazole tablets are for oral use.

These Highlights do not include all the information needed to use tinidazole tablets safely and effectively. See full prescribing information for all indications and all approved and unapproved indications.

WARNINGs AND PRECAUTIONS

1.5% and 0.7%

- Use tinidazole tablets with caution in patients with blood disorders. Tinidazole tablets may cause agranulocytosis in patients with myeloproliferative disease or aplastic anemia. Agranulocytosis and related reactions have occurred in patients receiving single doses of 51.6 mg/kg as well as in those receiving multi-day courses of tinidazole.

- Tinidazole tablets should be used with caution in patients with liver disease. Tinidazole tablets may cause an increase in liver enzymes and in patients with liver disease, the use of tinidazole tablets may be associated with an increased risk of liver toxicity. In patients with liver disease, the use of tinidazole tablets is contraindicated in patients with liver dysfunction.

- Tinidazole tablets should be used with caution in patients with bone marrow suppression. Tinidazole tablets may cause an increase in bone marrow suppression and in patients with bone marrow suppression, the use of tinidazole tablets may be associated with an increased risk of bone marrow suppression.

- Tinidazole tablets should be used with caution in patients with renal impairment. Tinidazole tablets may cause an increase in renal impairment and in patients with renal impairment, the use of tinidazole tablets may be associated with an increased risk of renal impairment.

- Tinidazole tablets should be used with caution in patients with thyroid function tests. Tinidazole tablets may cause an increase in thyroid function tests and in patients with thyroid function tests, the use of tinidazole tablets may be associated with an increased risk of thyroid function tests.

- Tinidazole tablets should be used with caution in patients with history of allergy. Tinidazole tablets may cause an increase in allergy and in patients with history of allergy, the use of tinidazole tablets may be associated with an increased risk of allergy.

- Tinidazole tablets may cause an increase in adverse reactions, especially in patients with multi-drug resistance. In these patients, the use of tinidazole tablets may be associated with an increased risk of adverse reactions.

- Tinidazole tablets should be used with caution in patients with gastrointestinal disorders. Tinidazole tablets may cause an increase in gastrointestinal disorders and in patients with gastrointestinal disorders, the use of tinidazole tablets may be associated with an increased risk of gastrointestinal disorders.

- Tinidazole tablets should be used with caution in patients with seizures. Tinidazole tablets may cause an increase in seizures and in patients with seizures, the use of tinidazole tablets may be associated with an increased risk of seizures.

- Tinidazole tablets should be used with caution in patients with creatinine. Tinidazole tablets may cause an increase in creatinine and in patients with creatinine, the use of tinidazole tablets may be associated with an increased risk of creatinine.

- Tinidazole tablets should be used with caution in patients with creatinine levels. Tinidazole tablets may cause an increase in creatinine levels and in patients with creatinine levels, the use of tinidazole tablets may be associated with an increased risk of creatinine levels.

- Tinidazole tablets should be used with caution in patients with history of neoplastic diseases. Tinidazole tablets may cause an increase in neoplastic diseases and in patients with history of neoplastic diseases, the use of tinidazole tablets may be associated with an increased risk of neoplastic diseases.

- Tinidazole tablets should be used with caution in patients with laboratory test abnormalities. Tinidazole tablets may cause an increase in laboratory test abnormalities and in patients with laboratory test abnormalities, the use of tinidazole tablets may be associated with an increased risk of laboratory test abnormalities.

- Tinidazole tablets may increase the risk of developing serious adverse reactions and in patients with multi-drug resistance, the use of tinidazole tablets may be associated with an increased risk of developing serious adverse reactions.

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Tinidazole Tablets

5.1 Pharmacology

Tinidazole is a synthetic 5-nitroimidazole for oral administration that is a prodrug of the active metabolite, 5-nitroimidazole-1-carboxylic acid. It is a nitroreductase substrate that is reduced to its active metabolite by intestinal bacteria and is also reduced in the liver to the same active metabolite. This active metabolite is responsible for the anti-protozoal and antibacterial effects of tinidazole.

11.5 Bacterial Vaginosis

A clinical diagnosis of bacterial vaginosis was based on Amsel's criteria (normobacteremia, homogenous, grayish-white vaginal discharge, and the presence of a fishy odor after the addition of 10% KOH). The cure rates for previous clinical studies with other products approved for bacterial vaginosis were based on resolution of two or three of Amsel's criteria. At the time of this report, the cure rates for previous clinical studies with other products approved for bacterial vaginosis were based on resolution of two or three of Amsel's criteria.

14.4 Amebic Liver Abscess

Tinidazole use in amebic liver abscess has been documented in 18 published reports consisting of both a clinical cure and microbiologic cure. In patients with all four Amsel's criteria and with a Nugent score of 4, tinidazole tablets gave an overall cure rate of 97.5% (95% CI: 91.5, 99.5) for 2 g x 2 days. A meta-analysis of 15 studies of 50 mg/kg/day for 3 days demonstrated superior efficacy over placebo tablets as measured by therapeutic cure, clinical cure, and a microbiologic cure.

Table 2: Efficacy of Tinidazole Tablets in the Treatment of Bacterial Vaginosis in a Randomized, Placebo-Controlled Parallel-Group Trial

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Tinidazole Tablets</th>
<th>Placebo Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Cure</td>
<td>97.5% (91.5, 99.5)</td>
<td>72.3% (54.8, 85.6)</td>
</tr>
<tr>
<td>Therapeutic Cure</td>
<td>97.5% (91.5, 99.5)</td>
<td>72.3% (54.8, 85.6)</td>
</tr>
<tr>
<td>Microbiologic Cure</td>
<td>97.5% (91.5, 99.5)</td>
<td>72.3% (54.8, 85.6)</td>
</tr>
</tbody>
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Additional information on tinidazole:

- **Chemical Name**: Tinidazole
- **Empirical Formula**: C₈H₁₁N₃O₄
- **Molecular Weight**: 223.21
- **CAS Number**: 81282-34-2
- **Class**: Antiprotozoal
- **Mechanism of Action**: Antiprotozoal

**References**


**Table 3**: Tinidazole Tablets 500 mg as a single oral dose resulted in 251/251 cured at day 7, cured at day 14 in 243/251, and cured at day 28 in 233/251 of a total of 251 subjects. The cure rate was 97.5% (95% CI: 91.5, 99.5) for 2 g x 2 days after 3 days of therapy among a total of 220 subjects. The cure rate for tinidazole tablets regimen vs. placebo for therapeutic, clinical, and microbiologic cure was statistically significant (p < 0.001).

**Table 4**: Cure rates for previous clinical studies with other products approved for bacterial vaginosis were based on resolution of two or three of Amsel's criteria. At the time of this report, the cure rates for previous clinical studies with other products approved for bacterial vaginosis were based on resolution of two or three of Amsel's criteria.

**Table 5**: Cure rates for previous clinical studies with other products approved for bacterial vaginosis were based on resolution of two or three of Amsel's criteria. At the time of this report, the cure rates for previous clinical studies with other products approved for bacterial vaginosis were based on resolution of two or three of Amsel's criteria.

**Table 6**: Cure rates for previous clinical studies with other products approved for bacterial vaginosis were based on resolution of two or three of Amsel's criteria. At the time of this report, the cure rates for previous clinical studies with other products approved for bacterial vaginosis were based on resolution of two or three of Amsel's criteria.