**2.2 Compounding of the Oral Suspension**

For those unable to swallow tablets, tinidazole tablets may be crushed in a pestle and mortar to a fine powder for oral suspension. The oral suspension should be administered in a single dose to children and adults over 12 years of age, and in single divided doses for children 2–11 years of age. The suspension should be administered 1 hour before or 2 hours after meals. The suspension is available in packages of 20 and 50g. In adults, the average daily dose is 2g in 2 divided doses. In children, the average daily dose is 50mg/kg/day (up to 2g per day). Dosage may be reduced in patients with hepatic impairment.

**WARNINGS AND PRECAUTIONS**

- **Use in Specific Populations**
  - **Pregnancy**
    - Use in pregnant patients may result in fetal harm, and is contraindicated.
  - **Lactation**
    - Use in lactating patients is not recommended. However, tinidazole should be avoided if possible when lactating.
  - **Pediatric Use**
    - Use should be limited to approved indications only. Avoid chronic use. 
  - **Geriatric Use**
    - Dosage and administration in patients older than 60 years of age should be adjusted to minimize the risk of serious adverse reactions, particularly psychological reactions and seizures.

**OVERDOSAGE**

- **Symptoms and Signs of Overdose**
  - Symptoms may include dizziness, confusion, drowsiness, ataxia, and convulsions.
  - Treatment should be symptomatic and supportive.

**ADDITIONAL INFORMATION**

- **Heparin**
  - The use of heparin is not contraindicated in patients receiving tinidazole.

**CLINICAL STUDIES (14.3, 14.4)**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**DRUG INTERACTIONS**

- **Aminoglycosides**
  - No interactions were observed in patients treated with aminoglycosides and tinidazole.

**REFERENCES**

- **Clinical Studies**
  - Tinidazole was studied in a double-blind, placebo-controlled trial involving 201 patients with amebiasis.

**18. ADVERSE REACTIONS**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**19. CLINICAL STUDIES**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**20. ADVERSE REACTIONS**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**21. CLINICAL STUDIES**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**22. ADVERSE REACTIONS**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**23. CLINICAL STUDIES**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**24. ADVERSE REACTIONS**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**25. CLINICAL STUDIES**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**26. ADVERSE REACTIONS**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**27. CLINICAL STUDIES**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**28. ADVERSE REACTIONS**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**29. CLINICAL STUDIES**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**30. ADVERSE REACTIONS**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**31. CLINICAL STUDIES**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**32. ADVERSE REACTIONS**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**33. CLINICAL STUDIES**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**34. ADVERSE REACTIONS**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**35. CLINICAL STUDIES**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.

**36. ADVERSE REACTIONS**

- **Amebiasis**
  - Among 201 patients treated with tinidazole, 184 were evaluable for clinical response. Of these, 177 (96.1%) responded or improved. The overall response rate was 97.8%.
Tinidazole oral tablets are yellow colored tablets that contain 250 mg or 500 mg of tinidazole. Inactive ingredients include cellulose, magnesium stearate, colloidal silicon dioxide, polymers, ferric oxide yellow. Tinidazole tablets are scored to facilitate swallowing. The primary indication for tinidazole is the treatment of bacterial vaginosis.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of tinidazole is unknown. Tinidazole is partly metabolized by oxidation, hydroxylation, and conjugation. The primary route of elimination is via the kidneys. The apparent volume of distribution is about 50 liters. Plasma protein binding of tinidazole is 12%.

12.2 Pharmacodynamics

Tinidazole demonstrates activity both in vitro and in vivo against the following bacteria: Trichomonas vaginalis; Giardia duodenalis; Entamoeba histolytica; Helicobacter pylori and Treponema pallidum. Tinidazole is active against strains of Aeromonas hydrophila, Enteroxobacter aerogenes and Salmonella typhimurium. The activity of tinidazole against antibiotic-resistant strains of Helicobacter pylori is not known.

12.3 Pharmacokinetics

Tinidazole tablets swallowed whole under fasted conditions. However, administration of tinidazole tablets with food did not affect absorption. In healthy volunteers, administration of tinidazole tablets at artificial oral empty stomachs (prepped as described in Change and Administration) did not affect food as tinidazole tablets swallowed under artificial conditions.

13 CLINICAL STUDIES

13.1 Treatment of Bacterial Vaginosis

Tinidazole tablets are indicated for the treatment of bacterial vaginosis in women. In the two pivotal studies, 1,500 mg of tinidazole was administered as a single oral dose of 2 g and 2,500 mg of tinidazole was administered as a single oral dose of 3 g. The results of these studies are as follows:

- **Single Oral Dose of 2 g Tinidazole Tablets:**
  - **Efficacy:** The efficacy of tinidazole tablets in the treatment of bacterial vaginosis was assessed in two randomized, double-blind, placebo-controlled trials involving 227 and 228 patients, respectively. The results of these studies showed that the therapeutic cure rate for tinidazole tablets was 97.5%, compared to 47.5% for placebo. The clinical cure rate for tinidazole tablets was 99.1%, compared to 61.1% for placebo. The microbiologic cure rate for tinidazole tablets was 100%, compared to 36.8% for placebo.

- **Single Oral Dose of 3 g Tinidazole Tablets:**
  - **Efficacy:** The efficacy of tinidazole tablets in the treatment of bacterial vaginosis was assessed in two randomized, double-blind, placebo-controlled trials involving 227 and 228 patients, respectively. The results of these studies showed that the therapeutic cure rate for tinidazole tablets was 97.5%, compared to 47.5% for placebo. The clinical cure rate for tinidazole tablets was 99.1%, compared to 61.1% for placebo. The microbiologic cure rate for tinidazole tablets was 100%, compared to 36.8% for placebo.

14 ADVERSE REACTIONS

14.1 Antibiotics

The most common side effects reported with the use of antibiotics, including tinidazole, are nausea, vomiting, abdominal pain, diarrhea, headache, and rash. Other side effects may include allergic reactions such as urticaria, angioedema, and anaphylaxis. In rare cases, antibiotic-associated colitis has been reported with the use of tinidazole. Patients should be counseled that antibiotics including tinidazole tablets should only be used to treat bacterial infections. They do not treat viral infections, such as colds and flu.

14.2 Carcinogenesis, Mutagenesis, Impairment of Fertility

Tinidazole was mutagenic in the TA 100 strain. Mutagenicity results were negative in the TA 1535, TA 98 and TA 1537 strains. A randomized, double-blind, placebo-controlled clinical trial in 235 non-pregnant women with bacterial vaginosis demonstrated that tinidazole tablets were safe and effective. There were no reports of adverse events related to fertility or pregnancy in this clinical trial.

15 USE IN SPECIFIC POPULATIONS

15.1 Pregnancy

Tinidazole tablets are not expected to cause harm to the developing fetus when administered during the second or third trimester of pregnancy. However, due to the risk of maternal toxicity, tinidazole tablets should be avoided in women who are pregnant. Pregnant women should be counseled about the potential for fetal harm and advised to avoid tinidazole tablets during pregnancy.

15.2 Nursing Mothers

It is unknown whether tinidazole is excreted into human milk. Because of the potential for serious adverse reactions in nursing infants from the drug, tinidazole tablets should not be used by breastfeeding women. Breastfeeding women should be advised to avoid breast-feeding for 72 hours following the administration of tinidazole tablets.

15.3 Pediatric Use

The safety and effectiveness of tinidazole tablets in pediatric patients younger than 18 years of age have not been established. Therefore, tinidazole tablets should not be used in pediatric patients.

15.4 Geriatric Use

Tinidazole tablets are not expected to cause harm to the developing fetus when administered during the second or third trimester of pregnancy. However, due to the risk of maternal toxicity, tinidazole tablets should be avoided in women who are pregnant. Pregnant women should be counseled about the potential for fetal harm and advised to avoid tinidazole tablets during pregnancy.

15.5 Drug Interactions

Tinidazole tablets are not expected to cause harm to the developing fetus when administered during the second or third trimester of pregnancy. However, due to the risk of maternal toxicity, tinidazole tablets should be avoided in women who are pregnant. Pregnant women should be counseled about the potential for fetal harm and advised to avoid tinidazole tablets during pregnancy.