Oblong, scored, white compressed tablets debossed with "Metronidazole tablets USP, 500 mg are available as follows:

- 100 (10 cards of 10 tablets each).
- 25 (25 cards of 1 tablet each).

NDC 17070-217-01 - Unit dose blister packages of 100 (10 cards of 10 tablets each).
NDC 17070-216-10 - Robotic Ready blister packages of 25 (25 cards of 1 tablet each).

DESCRIPTION

Metronidazole is an oral synthetic antiprotozoal and antibacterial agent derived from the chemical compound nitroimidazole, which has the following structural formula:

\[
\text{CH}_2\text{CH}_2\text{OH}
\]

Metronidazole tablets USP, 250 mg and 500 mg tablets USP for oral administration, contain the inert ingredients calcium hydrogen phosphate dihydrate, hydroxypropyl methylcellulose, lactose, magnesium stearate and sodium starch glycolate, and stearic acid.

CLINICAL PHARMACOLOGY

Absorption and distribution: Metronidazole is well absorbed from the gastrointestinal tract. Following oral administration, metronidazole is well absorbed, with peak plasma concentrations occurring between one and two hours after administration. Plasma concentrations of metronidazole are proportional to the administered dose. Following oral administration of 250 mg, 500 mg, or 2,000 mg produced peak plasma concentrations of 8 mcg/mL, 12 mcg/mL, and 40 mcg/mL, respectively. Studies reveal no significant bioavailability differences between males and females; however, because of weight differences, the resulting plasma levels in males are generally lower.

Metronidazole appears in cerebrospinal fluid, saliva, and feces following oral administration. In patients with disturbed gastric acid secretion or who are taking concurrent medications that may impair absorption such as sucralfate, peak plasma concentrations are generally lower than those obtained in patients without such interference. Metronidazole is well absorbed following oral administration when administered at the same time as food, and clinical trials have shown that absorption is not affected by food when administered with food. However, food alters the absorption of the second dose of metronidazole when it is administered twice daily. Oral metronidazole tablets are not absorbed following intravenous administration.

In volunteers, the bioavailability of metronidazole tablets is not affected by food (liquid, solid, or semi-solid). Absorption of metronidazole tablets is not significantly altered by the concurrent administration of carbonic anhydrase inhibitors, antacids, and metronidazole, and other nonabsorbed substances. The results of studies on drug interactions of metronidazole tablets USP with food are essentially the same as those of the tablets alone.

Metronidazole 500 mg tablets USP are indicated in the treatment of infections caused by susceptible anaerobic bacteria.

CLINICAL INDICATIONS

Anaerobic infections

See INDICATIONS AND USAGE section.

Infections caused by susceptible anaerobic bacteria are usually characterized by their gram-negative anaerobic or microaerophilic morphology. To control anaerobic infections, it is necessary to determine the causative organisms and their susceptibility to metronidazole; then the appropriate antimicrobial therapy should be used in addition to metronidazole tablets USP. Metronidazole tablets USP are indicated in the treatment of infections caused by anaerobic bacteria.

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although it is common to feel better early in the course of the treatment. (See metronidazole tablets and for at least one day afterward.

Alcoholic beverages should be avoided while taking metronidazole and requires treatment with a candicidal agent.

Accordingly, for such patients, doses below those usually selected or modifying antibacterial therapy. In the absence of selectivity, increasing the dosage of metronidazole may not improve the effectiveness of the drug. Metronidazole may interfere with certain types of enzymatic coupling of the assay to oxidation-reduction (e.g., NADH).

Pregnancy category B

Other: 

Cesarean delivery patients are less likely to be exposed to metronidazole for the period of time following delivery. The dose of metronidazole tablets should not be specifically reduced in acne patients since accelerated metabolism may not be achieved by metronidazole. (continued)
Metronidazole is an oral synthetic antiprotozoal and antibacterial agent. It possesses direct trichomonacidal and amebacidal activity against the following organisms:

- **Anaerobic gram-negative bacilli**, including:
  - *Bacteroides* species,
  - *Bacteroides vulgatus*,
  - *Bacteroides fragilis* group,
  - *Clostridium* species,
  - *Clostridium perfringens*,
  - *Clostridium novyi* group,
  - *Fusobacterium* species,
  - *Peptococcus* species,
  - *Peptostreptococcus* species.

- **Anaerobic gram-positive cocci**, including:
  - *Streptococcus* species,
  - *Streptococcus bovis*,
  - *Streptococcus pneumoniae*.

- **Anaerobic gram-positive bacilli**, including:
  - *Eubacterium* species,
  - *Fusobacterium* species,
  - *Peptococcus* species,
  - *Peptostreptococcus* species.

- **Anaerobic Bacteria**, National Committee for Clinical Microbiology and Quality Control in Laboratory Standards, and S. C. Lall and J. H. N. M. P. 1971; 2: 587-591; or

- **Microbiology**
  - **Susceptibility Tests**
    - The test of susceptibility to antibacterial drugs is a standardized agar dilution method and a broth microdilution method are used. Each time the test is performed, one or more control strains are recommended for standardized testing. Each strain is tested in a dilution series of metronidazole. The minimal inhibitory concentration (MIC) for most strains of these organisms is 1 mcg/mL or less.
  - **Clinical Pharmacology**
    - **Pharmacokinetics**
      - **Metabolism**
        - Metronidazole is the major component appearing in the blood and is similar to both oral and intravenous dosage forms, with an elimination half-life of five to eight hours.
        - The major route of elimination of metronidazole and its metabolites is via the urine (90 to 98% of the dose, with fecal excretion accounting for 1 to 15% of the dose). The metabolites that appear in the urine result primarily from side-chain oxidation [1- (hydroxyethyl)-2-hydroxymethyl-5-nitroimidazole and 2-ethyl-5-nitroimidazole (N-ethyl acid)] and glucuronide conjugation, with unchanged metronidazole accounting for approximately 20% of the total. Renal clearance of metronidazole is approximately 10 mL/min/1.73 m2.

  - **Excretion**
    - Metronidazole is excreted in the feces and urine in concentrations similar to those found in plasma. Metabolic concentrations of metronidazole have also been detected in the fat of breast abscesses.

  - **Indications and Usage**
    - **Therapeutic Uses**
      - **Anaerobic Bacterial Infections**
        - Metronidazole tablets USP are indicated for the treatment of anaerobic bacterial infections in female patients and are established by the administration of 250 mg or more of metronidazole at least 0.25 mg/kg/m2. Dosage adjustment is necessary in patients with decreased renal function. Metronidazole is given intravenously at a rate of 400 to 800 mg/m2 per day divided equally in two 12-hour periods. Suitable sterile solutions are infused through a suitable intravenous catheter. Metronidazole is not recommended for use in children under the age of 12 years. Metronidazole may be used in patients with impaired renal function; however, the dosage should be reduced to the extent of the impaired function.

    - **Gynecologic Infections**, including endometritis, tubo-ovarian infections, and postoperative abscesses.

    - **Trichomonas vaginalis**
      - Metronidazole is active against *Trichomonas vaginalis*. The dose is 250 mg two times a day for five days.

  - **Side Effects**
    - **Metabolism**
      - Metabolism of metronidazole is decreased in patients with decreased renal function. Metronidazole is given intravenously at a rate of 400 to 800 mg/m2 per day divided equally in two 12-hour periods. Suitable sterile solutions are infused through a suitable intravenous catheter. Metronidazole is not recommended for use in children under the age of 12 years. Metronidazole may be used in patients with impaired renal function; however, the dosage should be reduced to the extent of the impaired function.

    - **Elimination**
      - **Renal**
        - Metronidazole is eliminated primarily by way of the kidneys and is removed in the urine. The renal clearance is decreased in patients with impaired renal function.

    - **Pharmacokinetics**
      - Metronidazole is well absorbed following oral administration, and peak plasma concentrations occurring between one and two hours after administration. Plasma concentrations of metronidazole are proportional to the administered dose. The average plasma concentrations of 250 mg, 500 mg, or 2.0 gm of prophylactic plasma concentrations of 8 mg/mL, 12 mg/mL, and 40 mg/mL, respectively. Studies show no significant bioavailability differences between males and females; however, because of weight differences, the resulting plasma levels in males are generally lower.

    - **Dosage and Administration**
      - Metronidazole is administered orally. The usual adult dose is 250 mg three times a day for 7 to 10 days. In severe infections, the dose may be increased to 500 mg three times a day for 7 to 10 days. The dosage may be decreased in patients with impaired renal function.

    - **Contraindications**
      - Metronidazole is contraindicated in patients with a history of sensitivity to metronidazole or to other nitroimidazoles.