Metronidazole Injection, USP 500 mg/100 mL (5 mg/mL) Single Dose Container For Intravenous Use Only

To reduce the development of drug-resistant bacteria and maintain the effectiveness of this and other antibacterial drugs, Metronidazole Injection, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When determining the susceptibility of other bacteria to Metronidazole Injection, USP, other in vitro test methods may be used. However, these should be correlated with standard reference tests (e.g., disk or broth dilution) for Streptococcus species, Bacteroides group, and Peptostreptococcus species before these procedures are adopted routine laboratories.

INDICATIONS AND USAGE
Metronidazole Injection, USP is indicated for the treatment of serious infections caused by susceptible anaerobic bacteria. Because clinical disregarding susceptibility test interpretive criteria and

Metronidazole Injection, USP is indicated in the treatment of serious infections caused by susceptible anaerobic bacteria. Suitable candidates for this indication include the treatment of intra-abdominal infections, burn wound infections, pelvic infections, skin and skin structure infections, and gynecologic infections caused by Bacteroides group, Peptostreptococcus species, Peptococcus species, and Eubacterium species. Adverse reactions or sequelae of treatment with Metronidazole Injection, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When determining the susceptibility of other bacteria to Metronidazole Injection, USP, other in vitro test methods may be used. However, these should be correlated with standard reference tests (e.g., disk or broth dilution) for Streptococcus species, Bacteroides group, and Peptostreptococcus species before these procedures are adopted routine laboratories.

Metronidazole Injection, USP is indicated for use in anaerobic bacterial infections caused by susceptible anaerobic bacteria. Bacteriologic evaluations of clinical materials before and after therapy should be performed to determine the etiologic agent and its susceptibility to Metronidazole Injection, USP. Metronidazole Injection, USP may be used for the treatment of anaerobic infections that have been clinically diagnosed but in which the causative organism has not been identified. In such infections, the causative agents should be presumed to be susceptible to Metronidazole Injection, USP, and the drug should be administered for a sufficient period of time to achieve clinical healing. In any situation in which anaerobic bacteria or other susceptible microorganisms are suspected as the cause of infection, the causative organism should be isolated and identified, and its susceptibility to Metronidazole Injection, USP should be determined.

RECOMMENDATIONS AND CAUTIONS
1. The use of Metronidazole Injection, USP should be reserved for the treatment of serious infections caused by susceptible anaerobic bacteria. Because clinical disregarding susceptibility test interpretive criteria and

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Patients with severe hepatic disease metabolize metronidazole slowly, with resultant accumulation of metronidazole and its metabolite in the plasma. Accordingly, for such patients, use of metronidazole is contraindicated. Close monitoring of plasma metronidazole levels and toxicity is recommended.

In patients receiving metronidazole therapy in unique surgical situations, possible interactions with dehydrogenases (e.g., microorganisms) may produce unexpected systemic effects. The interactions are not known to occur with human dehydrogenases.

The dose of Metronidazole Injection, USP should not be reduced or drastically reduced in elderly patients since altered metabolism and reduced excretion may be reduced by one-half or more.

For practical purposes, use to prevent postoperative infection in an antiseptic or potentially antibiotic controlled surgery, the recommended dosage should be reduced from 0.8 mg/kg to 0.5 mg/kg.

The usual duration of therapy is 7 to 10 days; however, if infection is the bone and joint, lower respiratory tract, or ear, the duration of therapy may be longer.