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Metronidazole is an antibacterial drug. In animals, the 5-nitro group of metronidazole is reduced by metabolically active gut flora. The mean maximum serum concentration of metronidazole was approximately 125,000 ng/hr/mL after a single intravaginal dose of 5 grams of metronidazole vaginal gel and approximately 2,797 to 10,515 ng/hr/mL after a single 500 mg oral dose of metronidazole. This AUC (0-∞) is approximately 5% of the reported AUC after a 500 mg oral dose of metronidazole.

For the 500 mg oral dose, the mean terminal elimination half-life is approximately 12 hours.

The mean peak serum concentration of metronidazole after a single intravaginal dose of metronidazole vaginal gel was 6,000 ng/mL. After a single intravaginal dose of metronidazole vaginal gel, a mean maximum serum concentration of 214 ng/mL on day one and 294 ng/mL (range: 172 to 396 ng/mL) on day two was observed. The mean Cmax was approximately 2% of the mean maximum serum concentration reported in a human clinical study of this product.

Metronidazole is an antibacterial agent active against most strains of the 
Bacteroides spp. and 
Gardnerella vaginalis 
that cause vaginosis pathogens, 
Lactobacillus spp. (a general anaerobic aerobic flora), 
and 
streptococcal species. Metronidazole has shown evidence of carcinogenic activity after chronic oral treatment in mice and hamsters at doses approximately 5 times the clinical human dose based on body surface area comparison. Malignant liver tumors were reported in male mice dosed at 500 mg/kg/day (about 5 times the clinical human dose based on body surface area). Two lifetime tumorigenicity studies in hamsters have been performed and reported to be negative. Although no lifetime studies were performed to evaluate the carcinogenic potential of VANDAZOLE (metronidazole gel 0.75%), published data have shown that intravaginal administration of a topical formulation of metronidazole vaginal gel 0.75% for 5 days was noncarcinogenic in the female athymic rat (equivalent to 37.5 mg of metronidazole) to 38 healthy female subjects, a mean therapeutic cure rate: 2.8% to 21.0%.

The therapeutic cure rate was 42.8% for the VANDAZOLE group and 30.9% for the comparator group (95% confidence interval about the 11.9% difference in the cure rate between VANDAZOLE and the comparator group is 4.3% to 20.9% for the cure rate based on clinical success).

The comparator group (95% confidence interval about the 11.9% difference in the cure rate between VANDAZOLE and the comparator group is 4.3% to 20.9% for the cure rate based on clinical success). The comparator group received a single intravaginal dose of 200 mg enoxacin vaginal gel as a single intravaginal 5 gram dose of metronidazole vaginal gel 0.75%, a mean maximum serum concentration of 214 ng/mL on day one and 294 ng/mL (range: 172 to 396 ng/mL) on day two was observed. The mean Cmax was approximately 2% of the mean maximum serum concentration reported in a human clinical study of this product.

Metronidazole is an antibacterial drug. In animals, the 5-nitro group of metronidazole is reduced by metabolically active gut flora. The mean maximum serum concentration of metronidazole was approximately 125,000 ng/hr/mL after a single intravaginal dose of 5 grams of metronidazole vaginal gel and approximately 2,797 to 10,515 ng/hr/mL after a single 500 mg oral dose of metronidazole. This AUC (0-∞) is approximately 5% of the reported AUC after a 500 mg oral dose of metronidazole.

For the 500 mg oral dose, the mean terminal elimination half-life is approximately 12 hours.

The mean peak serum concentration of metronidazole after a single intravaginal dose of metronidazole vaginal gel was 6,000 ng/mL. After a single intravaginal dose of metronidazole vaginal gel, a mean maximum serum concentration of 214 ng/mL on day one and 294 ng/mL (range: 172 to 396 ng/mL) on day two was observed. The mean Cmax was approximately 2% of the mean maximum serum concentration reported in a human clinical study of this product.

Metronidazole is an antibacterial drug. In animals, the 5-nitro group of metronidazole is reduced by metabolically active gut flora. The mean maximum serum concentration of metronidazole was approximately 125,000 ng/hr/mL after a single intravaginal dose of 5 grams of metronidazole vaginal gel and approximately 2,797 to 10,515 ng/hr/mL after a single 500 mg oral dose of metronidazole. This AUC (0-∞) is approximately 5% of the reported AUC after a 500 mg oral dose of metronidazole.

For the 500 mg oral dose, the mean terminal elimination half-life is approximately 12 hours.

The mean peak serum concentration of metronidazole after a single intravaginal dose of metronidazole vaginal gel was 6,000 ng/mL. After a single intravaginal dose of metronidazole vaginal gel, a mean maximum serum concentration of 214 ng/mL on day one and 294 ng/mL (range: 172 to 396 ng/mL) on day two was observed. The mean Cmax was approximately 2% of the mean maximum serum concentration reported in a human clinical study of this product.

Metronidazole is an antibacterial drug. In animals, the 5-nitro group of metronidazole is reduced by metabolically active gut flora. The mean maximum serum concentration of metronidazole was approximately 125,000 ng/hr/mL after a single intravaginal dose of 5 grams of metronidazole vaginal gel and approximately 2,797 to 10,515 ng/hr/mL after a single 500 mg oral dose of metronidazole. This AUC (0-∞) is approximately 5% of the reported AUC after a 500 mg oral dose of metronidazole.

For the 500 mg oral dose, the mean terminal elimination half-life is approximately 12 hours.

The mean peak serum concentration of metronidazole after a single intravaginal dose of metronidazole vaginal gel was 6,000 ng/mL. After a single intravaginal dose of metronidazole vaginal gel, a mean maximum serum concentration of 214 ng/mL on day one and 294 ng/mL (range: 172 to 396 ng/mL) on day two was observed. The mean Cmax was approximately 2% of the mean maximum serum concentration reported in a human clinical study of this product.

Metronidazole is an antibacterial drug. In animals, the 5-nitro group of metronidazole is reduced by metabolically active gut flora. The mean maximum serum concentration of metronidazole was approximately 125,000 ng/hr/mL after a single intravaginal dose of 5 grams of metronidazole vaginal gel and approximately 2,797 to 10,515 ng/hr/mL after a single 500 mg oral dose of metronidazole. This AUC (0-∞) is approximately 5% of the reported AUC after a 500 mg oral dose of metronidazole.

For the 500 mg oral dose, the mean terminal elimination half-life is approximately 12 hours.

The mean peak serum concentration of metronidazole after a single intravaginal dose of metronidazole vaginal gel was 6,000 ng/mL. After a single intravaginal dose of metronidazole vaginal gel, a mean maximum serum concentration of 214 ng/mL on day one and 294 ng/mL (range: 172 to 396 ng/mL) on day two was observed. The mean Cmax was approximately 2% of the mean maximum serum concentration reported in a human clinical study of this product.