METROPYX

Metronidazole Tablets BP 500 mg

Composition
Each film coated tablet contains
Metronidazole BP 500 mg
Excipients Q.S
Colour: Tartrazine

Pharmacodynamic properties
Pharmacotherapeutic group: Nitroimidazole derivativesATC Code: PO1A B01

Mechanism of action
Metronidazole has antiprotozoan and antibacterial effects. It is effects against *Trichomonasvaginalis, Gardnerellavaginalis* and other protazoa including *Entamoebahistolytica. Gardialamblia* and anaerobic bacteria.

Pharmacokinetic Properties

Absorption
METROPYX (Metronidazole) is readily absorbed following administration by mouth and bioavailability is 90-100%. Peak plasma concentrations occur after 20 minutes to 3 hours. Absorption may be delayed, but is not reduced overall by administration with food.

Distribution
METROPYX (Metronidazole) is widely distributed. It appears in most body tissues and fluids. It also crosses the placenta and rapidly enters foetal circulation. No more than 20% is bound to plasma proteins.

Biotransformation
METROPYX (Metronidazole) is metabolised in the liver by side-chain oxidation and glucuronide formation. The half-life of metronidazole is 6.5 ± 2.9 hours. The half-life of metronidazole is reported to be longer in neonates and in patients with severe liver disease.

Elimination
The majority of a dose of metronidazole is excreted in the urine, mainly as metabolites; a small amount appears in the faeces. Metronidazole can be used in chronic renal failure; it is rapidly removed from the plasma by dialysis. Metronidazole is excreted in milk but the intake of a suckling infant of a mother receiving normal dosage would be considerably less than the therapeutic dosage for infants

Therapeutic indications
METROPYX (Metronidazole) is active against a wide range of pathogenic micro-organisms, notably species of *Bacteroids, Fusobacteria, Clostridia, Eubacteria,* anaerobic cocci and *Gardnerellavaginalis.lt* is also active against *Trichomonasvaginalis, Entamoebahistolytica, Gardialamblia, Balantidium coliand Helicobacter pylori.*

Metronidazole is indicated in adults and children for the following indications:
Prevention of post-operative infections due to anaerobic bacteria, particularly species of *bacteroids* and anaerobic streptococci.
The treatment of septicaemia, bacteraemia, peritonitis, brain abscess, necrotising pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis and post-operative wound infections from which pathogenic anaerobes have been isolated.
Urogenital trichomoniasis in the female *(Trichomonasvaginalis),* and in man. Bacterial vaginosis (also known as non-specific vaginitis, anaerobic vaginosis or *Gardnerellavaginalis).*
All forms of amoebiasis (intestinal and extra-intestinal disease and asymptomatic cyst passers). Giardiasis.
Acute ulcerative gingivitis.
Acute dental infections *(eg:* acute pericoronitis and acute apical infections) Anaerobically-infected leg ulcers and pressure sores.

Treatment of *Helicobacter pylori* infection associated with peptic ulcer as part of triple therapy.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Posology and method of administration

Posology :

METROPYX (Metronidazole) Tablets should be taken during or after meals, swallowed with water and NOT CHEWED.
Elderly: Caution is advised in the elderly, particularly at high doses, although there is limited information available on modification of dosage.
Hepatic impairment: Caution is advised in patients with hepatic encephalopathy. One third of the daily dose given once a day should be considered .

Method of Administration
For oral administration.

Contraindications
Known hypersensitivity to nitroimidazoles,
Pregnancy - metronidazole should not be used in the first trimester in patients with trichomoniasis or bacterial vaginosis
Breast feeding should be discontinued for 12-24 hours when single high dose therapy is used

Overdose
Features: Nausea, vomiting, diarrhoea, anorexia, metallic taste, headache, dizziness and occasionally insomnia and drowsiness. Transiently increased liver enzyme activities have been reported rarely.
Transient epileptiform seizures have been reported following intensive or prolonged therapy. Other adverse effects occurring in these circumstances include peripheral motor neuropathy, blood dyscrasias and liver damage.
The combination of alcohol and metronidazole has been said to cause disulfiram type reactions in about 10% of individuals with sudden onset of excitement, giddiness, flushing, nausea, headache, hypotension and dyspnoea. However the mechanism of this reaction has been questioned.

Treatment:

Unlikely to be required.
Disulfiram type reactions should be treated with intravenous fluids and plasma expanders if necessary.

Symptomatic and supportive.

In more serious cases:

1. Single brief convulsions do not require treatment. If frequent or prolonged control with intravenous diazepam (10-20mg in adults; 0.1-0.3mg/kg body weight) or lorazepam (4mg in an adult and 0.05mg/kg in a child). Give oxygen and correct acid base and metabolic disturbances as required.
2. Other measures as indicated by the patient's clinical condition.

Special precautions for storage

Store in a cool & dry place.
Protect from light & moisture.
Keep all medicine out of reach of children.

Presentation

10 x 10 Tablets