PREVENT Tablets
(Tinidazole)

پریوینٹ گولیاں
(ٹینیڈازول)

Prevent Tablets 500 mg
Each film coated tablet contain: Tinidazole .....500 mg.
Product Complies U.S.P Specs.

Prevent Tablets 1 g
Each film coated tablet contain: Tinidazole .....1000 mg.
Product Complies U.S.P Specs.

CHEMICAL CLASSIFICATION
Tinidazole is a synthetic antiprotozoal agent. It is 1-[2-(ethylsulfonyl)ethyl]-2-methyl 5-nitromidazole, a second generation 2-methyl-5- nitromidazole.

PROPERTIES AND EFFECTS
Tinidazole (PREVENT) has been shown to have action against Protozoal and Anaerobic infections.

PHARMACOKINETICS
Absorption *:* After oral administration, tinidazole is rapidly and completely absorbed.

Distribution: Tinidazole is distributed into virtually all tissues and body fluids and also crosses the blood-brain barrier. The apparent volume of distribution is about 50 liters. Plasma protein binding of tinidazole is 12%.

Metabolism: Tinidazole, like Metronidazole, is significantly metabolized in humans prior to excretion. Tinidazole is partly metabolized by oxidation,hydroxylation and conjugation. Tinidazole is the major drug-related constituent in plasma after human treatment, along with a small amount of 2-hydroxymethyl metabolite.

Elimination: The plasma half-life of Tinidazole is approximately 12-14 hours. Tinidazole is excreted by the liver and the kidneys. Tinidazole is excreted in the urine mainly as unchanged drug(approximately 20-25% of the administered dose). Approximately 12% of the drug is excreted in the feces.

Renal Impairment: The pharmacokinetics of tinidazole in patients with severe renal impairment (CrCL<22 mL/min) are not significantly different from the pharmacokinetics seen in healthy subjects. However, during hemodialysis, clearance of Tinidazole is significantly increased; the half-life is reduced from 12.0 hours to 4.9 hours. Approximately 43% of the amount present in the body is eliminated during a 6-hour hemodialysis session. The pharmacokinetics of Tinidazole in patients undergoing routine continuous peritoneal dialysis has not been investigated.

Impaired Hepatic Function: There are no data on Tinidazole pharmacokinetics in patients with impaired hepatic function. Reduction of metabolic elimination of metronidazole, a chemically – related nitroimidazole, in patients with hepatic dysfunction has been reported in several studies.

INDICATIONS
1. Acute Ulcerative Gingivitis
2. Acute Dental Infections Caused By Anaerobes
3. Periodontitis
4. Odontogenic Abscesses

DOSAGE AND ADMINISTRATION

Anaerobic infections: Adults: Initial dose of 2 g on the first day followed by 1 g daily or 500 mg twice daily; usual duration of treatment: 5-6 days

Prevention of postoperative anaerobic infections: Adults: 2 g approximately 12 hours before surgery

Acute ulcerative gingivitis: Adults: A single dose of 2 g

Dose in children:
Safety and effectiveness in children below the age of 3 years have not been established

CONTRAINDICATIONS

Tinidazole is contraindicated in patients with hypersensitivity to tinidazole, any component of the tablet, or other nitroimidazole derivatives. Tinidazole is contraindicated during the first trimester of pregnancy.

UNDESIRABLE SIDE-EFFECTS

Central Nervous System: Two serious adverse reactions reported include convulsions and transient peripheral neuropathy including numbness and paresthesia. Other CNS reports include vertigo, ataxia, giddiness, insomnia, drowsiness.

Gastrointestinal: tongue discoloration, stomatitis, diarrhea

Hypersensitivity: urticaria, pruritis, rash, flushing, sweating, dryness of mouth, fever, burning sensation, thirst, salivation, angioedema

Renal: darkened urine

Cardiovascular: palpitations

Hematopoietic: transient neutropenia, transient leukopenia

Other: candida overgrowth, increased vaginal discharge, oral candidiasis, hepatic abnormalities including raised transaminase level, arthralgias, myalgias, arthritis

Rare reported adverse effects include bronchospasm, dypsnea, coma, confusion, depression, furry tongue, pharyngitis and reversible thrombocytopenia.

Adverse Reactions in Pediatric Patients:
Adverse events reported in pediatric patients taking tinidazole were similar in nature and frequency to adult findings ncluding nausea, vomiting, diarrhea, taste change, anorexia and abdominal pain.

PRECAUTIONS AND WARNINGS

Do not drink alcohol while taking this drug.
Clinical and laboratory monitoring is required if treatment is greater than 7 days.

PREGNANCY

As a general rule no drug should be administrated during the first trimester and or during the last month of pregnancy.

NURSING MOTHER

Tinidazole is excreted in breast milk in concentration similar to those in serum. Tinidazole can be detected in breast milk for up to 72 hours following administration. Interruption of breast-feeding is recommended during Tinidazole therapy and for three days following the last dose.

OVERDOSAGE

There are no reports of over doses with Tinidazole in humans.

Treatment of overdosage: There is no specific antidote for the treatment of overdosage with Tinidazole; therefore, treatment should be symptomatic and supportive. Gastric lavage may be helpful. Hemodialysis can be considered because approximately 43% of the amount present in the body is eliminated during a 6-hour hemodialysis session.

PRESENTATION

Prevent Tablet 500 mg: In blister pack of 5 x 10 tablets.
Prevent Tablet 1 g: In blister pack of 4 x 5 tablets.

STORAGE

Store below 30°C in a dry place, protect from light.
To be dispensed on the prescription of a registered medical practitioner only.
Keep out of the reach of children.

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:

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