Artwork Details

Product:	Metronidazole Tablets BP 250 mg
Exporting Country:	RWANDA
Artwork Code:	
Bar Code:	
Pack Type:	1000 Tablets
Date:	21.06.2022

Leaflet Packaging Details

Dimension:	125 mmx 255 mm
GSM:	60 GSM
Paper:	Maplitho Paper
Colour:	Single Colour Black
Side:	Two Side
Fold:	
Final Folding Size:	

125 mm

255 mm

Metronidazole Tablets BP 250 mg

COMPOSITION:
Each film coated tablet contains:

Metronidazole	BP	250 mg
Excipients		q.s.

Color : Tartrazine

INDICATION:
Symptomatic Trichomoniasis. Metronidazole tablets are indicated for the treatment of T. vaginalis infection in females and males when the presence of the trichomonad has been confirmed by appropriate laboratory procedures (wet smears and/or cultures).
Asymptomatic Trichomoniasis. Metronidazole tablets are indicated in the treatment of asymptomatic T. vaginalis infection in females when the organism is associated with endocervicitis, cervicitis, or cervical erosion. Since there is evidence that presence of the trichomonad can interfere with accurate assessment of abnormal cytological smears, additional smears should be performed after eradication of the parasite..
Amebiasis. Metronidazole tablets are indicated in the treatment of acute intestinal amebiasis (amebic dysentery) and amebic liver abscess. In amebic liver abscess, Metronidazole tablets therapy does not obviate the need for aspiration or drainage of pus.
Anaerobic Bacterial Infections. Metronidazole tablets are indicated in the treatment of serious infections caused by susceptible anaerobic bacteria. Indicated surgical procedures should be performed in conjunction with Metronidazole tablets therapy. In a mixed aerobic and anaerobic infection, antimicrobials appropriate for the treatment of the aerobic infection should be used in addition to Metronidazole tablets.
Intra-abdominal infections, including peritonitis, intra-abdominal abscess, and liver abscess, caused by Bacteroides species including the B. fragilis group (B. fragilis, B. distasonis, B. ovatus, B. thetaiotaomicron, B. vulgatus), Clostridium species, Eubacterium species, Peptococcus species, and Peptostreptococcus species.
Skin and skin structure infections caused by Bacteroides species including the B. fragilis group, Clostridium species, Peptococcus species, Peptostreptococcus species, and Fusobacterium species.
Gynecologic infections, including endometritis, endomyometritis, tubo-ovarian abscess, and postsurgical vaginal cuff infection, caused by Bacteroides species including the B. fragilis group, Clostridium species, Peptococcus species, Peptostreptococcus species, and Fusobacterium species.
Bacterial septicemia caused by Bacteroides species including the B. fragilis group and Clostridium species.
Bone and joint infections, (as adjunctive therapy), caused by Bacteroides species including the B. fragilis group.
Central nervous system (cns) infections, including meningitis and brain abscess, caused by Bacteroides species including the B. fragilis group.
Lower respiratory tract infections, including pneumonia, empyema, and lung abscess, caused by Bacteroides species including the B. fragilis group.
Endocarditis caused by Bacteroides species including the B. fragilis group.

DOSAGE:
Trichomoniasis:
In the Female: One-day treatment - two grams of metronidazole, given either as a single dose or in two divided doses of one gram each, given in the same day.
Seven-day course of treatment-250 mg three times daily for seven consecutive days. There is some indication from controlled comparative studies that cure rates as determined by vaginal smears and signs and symptoms, may be higher after a seven-day course of treatment than after a one-day treatment regimen.
The dosage regimen should be individualized. Single-dose treatment can assure compliance, especially if administered under supervision, in those patients who cannot be relied on to continue the seven-day regimen. A seven-day course of treatment may minimize reinfection by Further, some patients may tolerate one treatment regimen better than the other.
In the MaleTreatment should be individualized as it is for the female.
Amebiasis
Adults:
For acute intestinal amebiasis (acute amebic dysentery): 750 mg orally three times daily for 5 to 10 days.
For amebic liver abscess: 500 mg or 750 mg orally three times daily for 5 to 10 days.
Pediatric patients: 35 to 50 mg/kg/24 hours, divided into three doses, orally for 10 days.
Anaerobic Bacterial Infections
In the treatment of most serious anaerobic infections, intravenous metronidazole is usually administered initially.
The usual adult oral dosage is 7.5 mg/kg every six hours (approx. 500 mg for a 70-kg adult). A maximum of 4 g should not be exceeded during a 24-hour period.
The usual duration of therapy is 7 to 10 days; however, infections of the bone and joint, lower respiratory tract, and endocardium may require longer treatment.

POSSIBLE SIDE EFFECTS:
The following reactions have been reported during treatment with metronidazole:
Central Nervous System: The most serious adverse reactions reported in patients treated with metronidazole have been convulsive seizures, encephalopathy, aseptic meningitis, optic and peripheral neuropathy, the latter characterized mainly by numbness or paresthesia of an extremity. Since persistent peripheral neuropathy has been reported in some patients receiving prolonged administration of metronidazole, patients should be specifically warned about these reactions and should be told to stop the drug and report immediately to their physicians if any neurologic symptoms occur. In addition, patients have reported headache, syncope, dizziness, vertigo, incoordination, ataxia, confusion, dysarthria, irritability, depression, weakness, and insomnia
Gastrointestinal: The most common adverse reactions reported have been referable to the gastrointestinal tract, particularly nausea, sometimes accompanied by headache, anorexia, and occasionally vomiting; diarrhea; epigastric distress; and abdominal cramping and constipation.
Mouth: A sharp, unpleasant metallic taste is not unusual. Furry tongue, glossitis, and stomatitis have occurred; these may be associated with a sudden overgrowth of Candida which may occur during therapy.
Dermatologic: Erythematous rash and pruritus.
Hematopoietic: Reversible neutropenia (leukopenia); rarely, reversible thrombocytopenia.
Cardiovascular: QT prolongation has been reported, particularly when metronidazole was administered with drugs with the potential for prolonging the QT interval. Flattening of the T-wave may be seen in electrocardiographic tracings.
Hypersensitivity: Urticaria, erythematous rash, Stevens-Johnson Syndrome, toxic epidermal necrolysis, flushing, nasal congestion, dryness of the mouth (or vagina or vulva), and fever.
Renal: Dysuria, cystitis, polyuria, incontinence, and a sense of pelvic pressure. Instances of darkened urine have been reported by approximately one patient in 100,000. Although the pigment which is probably responsible for this phenomenon has not been positively identified, it is almost certainly a metabolite of metronidazole and seems to have no clinical significance.
Other: Proliferation of Candida in the vagina, dyspareunia, decrease of libido, proctitis, and fleeting joint pains sometimes resembling "serum sickness." Rare cases of pancreatitis, which generally abated on withdrawal of the drug, have been reported.

CONTRAINDICATIONS:
Hypersensitivity
Metronidazole Tablets are contraindicated in patients with a prior history of hypersensitivity to metronidazole or other nitroimidazole derivatives.
In patients with trichomoniasis, Metronidazole Tablets are contraindicated during the first trimester of pregnancy
Psychotic Reaction with Disulfiram
Use of oral metronidazole is associated with psychotic reactions in alcoholic patients who were using disulfiram concurrently. Do not administer metronidazole to patients who have taken disulfiram within the last two weeks
Interaction with Alcohol
Use of oral metronidazole is associated with a disulfiram-like reaction to alcohol, including abdominal cramps, nausea, vomiting, headaches, and flushing. Discontinue consumption of alcohol or products containing propylene glycol during and for at least three days after therapy with metronidazole

WARNINGS:
Encephalopathy and peripheral neuropathy
Cases of encephalopathy and peripheral neuropathy (including optic neuropathy) have been reported with metronidazole.
Encephalopathy has been reported in association with cerebellar toxicity characterized by ataxia, dizziness, and dysarthria. CNS lesions seen on MRI have been described in reports of encephalopathy. CNS symptoms are generally reversible within days to weeks upon discontinuation of metronidazole. CNS lesions seen on MRI have also been described as reversible.
Peripheral neuropathy, mainly of sensory type has been reported and is characterized by numbness or paresthesia of an extremity.
Convulsive seizures have been reported in patients treated with metronidazole.
Aseptic meningitis
Cases of aseptic meningitis have been reported with metronidazole. Symptoms can occur within hours of dose administration and generally resolve after metronidazole therapy is discontinued.
The appearance of abnormal neurologic signs and symptoms demands the prompt evaluation of the benefit/risk ratio of the continuation of therapy

PRECAUTIONS:
Hepatic Impairment
Patients with hepatic impairment metabolize metronidazole slowly, with resultant accumulation of metronidazole in the plasma. For patients with severe hepatic impairment (Child-Pugh C), a reduced dose of metronidazole is recommended. For patients with mild to moderate hepatic impairment, no dosage adjustment is needed but these patients should be monitored for metronidazole associated adverse events
Renal Impairment
Patients with end-stage renal disease may excrete metronidazole and metabolites slowly in the urine, resulting in significant accumulation of metronidazole metabolites. Monitoring for metronidazole associated adverse events is recommended
Fungal Superinfections
Known or previously unrecognized candidiasis may present more prominent symptoms during therapy with Metronidazole tablets and requires treatment with a candidacidal agent.
Use in Patients with Blood Dyscrasias
Metronidazole is a nitroimidazole and should be used with caution in patients with evidence of or history of blood dyscrasia. A mild leukopenia has been observed during its administration; however, no persistent hematologic abnormalities attributable to metronidazole have been observed in clinical studies. Total and differential leukocyte counts are recommended before and after therapy.
Drug-Resistant Bacteria and Parasites
Prescribing Metronidazole tablets in the absence of a proven or strongly suspected bacterial or parasitic infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria and parasites.
Information for Patients
Interaction with Alcohol
Discontinue consumption of alcoholic beverages or products containing propylene glycol while taking Metronidazole tablets and for at least three days afterward because abdominal cramps, nausea, vomiting, headaches, and flushing may occur.
Treatment of Bacterial and Parasitic Infections
Patients should be counseled that Metronidazole tablets should only be used to treat bacterial and parasitic infections. Metronidazole tablet does not treat viral infections (e.g., the common cold). When Metronidazole tablets are prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Metronidazole tablets in the future.

DRUG INTERACTIONS:
Disulfiram
Psychotic reactions have been reported in alcoholic patients who are using metronidazole and disulfiram concurrently. Metronidazole should not be given to patients who have taken disulfiram within the last two weeks
Alcoholic Beverages
Abdominal cramps, nausea, vomiting, headaches, and flushing may occur if alcoholic beverages or products containing propylene glycol are consumed during or following metronidazole therapy
Warfarin and other Oral Anticoagulants
Metronidazole has been reported to potentiate the anticoagulant effect of warfarin and other oral coumarin anticoagulants, resulting in a prolongation of prothrombin time. When Metronidazole tablets are prescribed for patients on this type of anticoagulant therapy, prothrombin time and INR should be carefully monitored.
Lithium
In patients stabilized on relatively high doses of lithium, short-term metronidazole therapy has been associated with elevation of serum lithium and, in a few cases, signs of lithium toxicity. Serum lithium and serum creatinine levels should be obtained several days after beginning metronidazole to detect any increase that may precede clinical symptoms of lithium intoxication.
Busulfan
Metronidazole has been reported to increase plasma concentrations of busulfan, which can result in an increased risk for serious busulfan toxicity. Metronidazole should not be administered concomitantly with busulfan unless the benefit outweighs the risk. If no therapeutic alternatives to metronidazole are available, and concomitant administration with busulfan is medically needed, frequent monitoring of busulfan plasma concentration should be performed and the busulfan dose should be adjusted accordingly.
Drugs that Inhibit CYP450 Enzymes
The simultaneous administration of drugs that decrease microsomal liver enzyme activity, such as cimetidine, may prolong the half-life and decrease plasma clearance of metronidazole.
Drugs that Induce CYP450 Enzymes
The simultaneous administration of drugs that induce microsomal liver enzymes, such as phenytoin or phenobarbital, may accelerate the elimination of metronidazole, resulting in reduced plasma levels; impaired clearance of phenytoin has also been reported.

Drugs that Prolong the QT interval
QT prolongation has been reported, particularly when metronidazole was administered with drugs with the potential for prolonging the QT interval.

DRIVING AND USING MACHINES:
Patients should be warned about the potential for drowsiness, dizziness, confusion, hallucinations, convulsions or transient visual disorders, and advised not to drive or operate machinery if these symptoms occur.

PREGNANCY AND LACTATION:
Teratogenic Effects:
There are no adequate and well controlled studies of Metronidazole tablets in pregnant women. There are published data from case-control studies, cohort studies, and 2 meta-analyses that include more than 5000 pregnant women who used metronidazole during pregnancy. Many studies included first trimester exposures. One study showed an increased risk of cleft lip, with or without cleft palate, in infants exposed to metronidazole in-utero; however, these findings were not confirmed. In addition, more than ten randomized placebo-controlled clinical trials enrolled more than 5000 pregnant women to assess the use of antibiotic treatment (including metronidazole) for bacterial vaginosis on the incidence of preterm delivery. Most studies did not show an increased risk for congenital anomalies or other adverse fetal outcomes following metronidazole exposure during pregnancy. Three studies conducted to assess the risk of infant cancer following metronidazole exposure during pregnancy did not show an increased risk; however, the ability of these studies to detect such a signal was limited.
Metronidazole crosses the placental barrier and its effects on the human fetal organogenesis are not known. Reproduction studies have been performed in rats, rabbits, and mice at doses similar to the maximum recommended human dose based on body surface area comparisons. There was no evidence of harm to the fetus due to metronidazole.
Nursing Mothers
Metronidazole is present in human milk at concentrations similar to maternal serum levels, and infant serum levels can be close to or comparable to infant therapeutic levels. Because of the potential for tumorigenicity shown for metronidazole in mouse and rat studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Alternatively, a nursing mother may choose to pump and discard human milk for the duration of metronidazole therapy, and for 24 hours after therapy ends and feed her infant stored human milk or formula.
Geriatric Use
In elderly geriatric patients, monitoring for metronidazole associated adverse events is recommended. Decreased liver function in geriatric patients can result in increased concentrations of metronidazole that may necessitate adjustment of metronidazole dosage
Pediatric Use
Safety and effectiveness in pediatric patients have not been established, except for the treatment of amebiasis.

STORAGE:
Store in a dry place, below 30°C, protect from light.
Keep medicines out of reach of children.

PRESENTATION:
1000 tablets packed in a jar along with leaflet .

MADE IN INDIA
Manufactured by:
Aura Lifecare Pvt. Ltd.
S. No. 254/14/1, Jarod-Savli Road,
P.O.: Karachiya, Tal. Savli,
Dist. Vadodara-391 520, Gujarat, India
(A WHO-GMP Certified Company)

Imported & Marketed by:
SUN ENTERPRISES LTD.
BP 1952 Kigali, Rwanda.

Department	Design	QA	QA	QC	Production	Factory Manager	QA Manager	General Manager
Name:								
Sign: Date:								