Klint® Tablets/Injection
(Metronidazole)

Klint® Suspension
(Metronidazole Benzoate)

COMPOSITION:
Klint® 400mg Tablets:
Each film coated tablet contains:
Metronidazole BP.....400mg

Klint® Injection:
Each 100ml contains:
Metronidazole BP..... 500mg

Klint® Suspension:
Each 5ml contains:
Metronidazole Benzoate BP
equivalent to Metronidazole.....200mg

INDICATIONS:
Klint® is indicated for the treatment of:
- Acute intestinal amoebiasis and amoebic liver abscess
- Giardiasis
- Symptomatic trichomoniasis in females and males; Asymptomatic trichomoniasis in females when associated with endocervicitis or cervical erosion;
- Acute ulcerative gingivitis and dental infections due to anaerobic bacteria
- Anaerobic infections due to sensitive strains of obligate anaerobes, such as Bacteroids spp; including the B. fragilis group. Fusobacterium spp; Clostridium spp; susceptible strains of Eubacterium; Peptococcus spp; and Peptostreptococcus spp;
- Preoperatively and postoperatively for prophylaxis of infection in patients undergoing surgical procedures which are classified as contaminated or potentially contaminated
- Balantidiasis

CONTRA-INDICATIONS:
Klint® is contra-indicated in patients with a prior history of hypersensitivity to Metronidazole or other nitroimidazole derivatives. It is contra-indicated in patients with history or evidence of blood dyscrasia

In patients with trichomoniasis, **Klint®** is contra-indicated during the first trimester of pregnancy (see precautions)

DOSAGE & ADMINISTRATION:
Do not exceed 4.0gm/24hours in adults or 50mg/kg/24hours in children. The tablets should be taken with or after meals. The suspension should be taken one hour before meals. For children, the recommended dose is 35-50mg/kg/day. Age related guidelines which follow are approximations based on average dose recommendations and must be adjusted to suit the individual patient

TABLETS:
Amoebiasis and symptomless cyst passers:
Amoebic liver abscess:
One tablet 3 times daily for 5 days
Urogenital trichomoniasis, Non-specific vaginitis, Giardiasis: One tablet 2 times daily for 5-7 days
Acute ulcerative gingivitis:
One tablet 2 times daily for 3 days
Or as directed by the physician

INJECTION:
Klint® Injection should be infused intravenously at an approximate rate of 5ml/min
Anaerobic Infections:
Adults: 500mg 8 hourly by IV Infusion
Children: 7.5mg/Kg 8 hourly
Or as directed by the physician

SUSPENSION:
For amoebiasis:
Children: 1–7 years: ½ teaspoon 3 times daily
7–10 years: 1 teaspoonful 3 times daily
Over 10 years and adults: 2 teaspoonfuls 3 times daily for 5–10 days
For giardiasis and acute ulcerative gingivitis:
Children: 1–7 years: ¼ to ½ teaspoon 3 times daily
Children: 7–10 years: ½ teaspoon 3 times daily
Over 10 years and adults: 1 teaspoonful 3 times daily
Im-mature children and babies weighing less than 11kg should receive proportionately smaller dosage
Or as directed by the physician

WARNINGS:
Convulsive seizures and peripheral neuropathy, the latter characterized by numbness or paraesthesia of an extremity, have been reported in patients treated with Metronidazole The appearance of abnormal neurologic signs requires immediate assessment of benefits of continued treatment weighed against the potential risks. Metronidazole should be administrated with caution to patients with central nervous system diseases

Metronidazole has been shown to be carcinogenic in mice and rats. While there is no evidence associating Metronidazole with tumors in man, use of the drug should be reserved for the conditions described in the INDICATIONS section

PRECAUTIONS:
(See also contra-indications):
If possible, when treating anaerobic infections susceptibility tests should be performed prior to initiation of therapy. An organism may be considered susceptible if the MIC value for Metronidazole is not more than 16mcg/ml

Slow metabolism in patients with hepatic disease results in increased plasma levels of Metronidazole and its metabolites

Indicated surgical procedures should be performed in conjunction with Metronidazole treatment, such as incision and drainage of an abscess. In a mixed aerobic and anaerobic infection, antibiotics appropriate for the treatment of the aerobic infection should be used in addition to Metronidazole. The drug is not effective against aerobic or facultative anaerobic organisms

Candida overgrowth may occur during therapy with Metronidazole and should be treated with a candicidal agent

A mild leukopenia has been observed during administration of Metronidazole; however, no persistent haematologic abnormalities attributable to Metronidazole have been observed. Total and differential leukocyte counts are recommended before and after therapy

Metronidazole has been reported to potentiate the activity of warfarin and other oral coumarin anticoagulants. There is no interaction with heparin

Patients receiving concurrent therapy of drugs inducing microsomal enzymes, such as phenytoin and phenobarbital, may metabolize Metronidazole at a much greater rate than normally, resulting in reduced plasma levels

Alcoholic beverages should not be consumed during Metronidazole therapy because abdominal cramps, nausea, vomiting, headaches and flushing may occur as a result of the blockade of acetaldehyde metabolism

Metronidazole may interfere with certain chemical analysis for aspartate aminotranferase (AST, SGOT), alanine aminotransferase (ALT, SGPT) triglycerides and glucose using the hexokinase method resulting in decreased values

Metronidazole crosses the placental barrier and enters the fetal circulation rapidly While it has not been shown to be teratogenic in either human or animals Metronidazole should be used in pregnant women only if clearly needed. Use of Metronidazole for trichomoniasis in the second and third trimesters should be restricted to those in whom local palliative treatment is inadequate to control symptoms

The drug also appears in breast milk in concentrations similar to those found in plasma If use of Metronidazole in a nursing woman is deemed essential, institution of alternate methods of infant feeding is recommended

ADVERSE REACTIONS:
In addition to those discussed above, the following reactions have been reported during treatment with Metronidazole:
Gastro-intestinal symptoms such as nausea, vomiting, abdominal discomfort and unpleasant metallic taste; reversible neutropenia; erythematous rash and pruritis; central nervous system effects such as headache, dizziness and syncope; fever; darkened urine, which appears to have no clinical significance; dysuria, cystitis or polyuria; flattening of the T-Wave in electrocardiographic tracings

OVER DOSAGE:
Single oral doses of Metronidazole upto 15gm, have been reported in overdoses Symptoms reported include nausea, vomiting, and ataxia

Oral Metronidazole has been studied as a radiation sensitizer in the treatment of malignant tumors. Neurotoxic effects, icluding seizures and peripheral neuropathy, have been reported after 5 - 7 days of doses of 6 - 10.4gm every other day

Treatment:
There is no specific antidote for Metronidozole overdose; therefore, management of the patient should consist of symptomatic and supportive therapy

PRESENTATIONS:
Klint® 400mg Tablet in pack of 10 x 15's
Klint® Injection in 100ml glass bottle with hanging device
Klint® Suspension in pack of 60ml bottle

INSTRUCTIONS:
Keep out of reach of children
Avoid exposure to heat, light and humidity
Store at 25°C or below
Improper storage may deteriorate the medicine

Avoid freezing and Injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particles

کلنٹ ٹیبلٹ / انجکشن
(میٹرونیڈازول)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
ہدایات: بچوں کی پہنچ سے دور رکھیں
دوا کو دھوپ، گرمی اور نمی سے محفوظ ۲۵°ڈگری سینٹی گریڈ
یا اس سے کم درجہ حرارت پر رکھیں ورنہ دوا خراب ہو جائے گی
تنبیہ: منجمد ہونے سے بچائیں اور انجکشن کے لیک ہونے، دھندلا ہونے
یا اس میں کوئی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں

کلنٹ سسپینشن
(میٹرونیڈازول بینزوایٹ)

Manufactured by:
SAMI PHARMACEUTICALS (PVT) LTD.
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