ACTION
The most outstanding pharmacological feature of this chemotherapeutic drug is its specific trichomonal activity, which is lethal to the causative organism Trichomonas vaginalis, but is devoid of destructive effect on the useful bacterial flora of the vagina (Doderlein’s bacillus), also its specific amoebicidal activity in cases of Amoebic dysentery and liver abscess due to Amoebic infestation. Metronidazole is also active against a broad spectrum of anaerobic bacteria including Bacteroides, Fusobacterium, Clostridium and various anaerobic cocci. The drug is rapidly absorbed orally and is mainly excreted in urine as unchanged form. This assures full availability of the drug against the flagellates of the urinary tract which cannot be reached by topical treatment alone. The oral route is also useful in cases of trichomonas urethritis of the male.

INDICATIONS
This medicinal product is indicated in the treatment of genito-urinary infections due to Trichomonas vaginalis, non-specific vaginitis, amebiasis, giardiasis, infections involving sensitive anaerobic micro-organisms.

DOSAGE AND ADMINISTRATION
In all cases, strictly follow the physician’s prescription.

Dosage
Trichomonas vaginalis vaginitis and urethritis
• Woman: either 250 mg by oral route twice daily associated to 1 Nidazole pessary per day by vaginal route, for 10 days, or 2 g by oral route in a single intake.
• Man: 250 mg by oral route twice daily for 10 days. Exceptionally the treatment could be increased to 0.750 g or to 1 g/day. Your partner must be treated simultaneously even if she/he does not demonstrate any clinical signs.

Non-specific vaginitis
500 mg by oral route twice daily for 7 days. Your partner must be treated simultaneously.

Amebiasis
• Adults: 1.5 g/day.
• Children: 30 to 40 mg/kg/day.
The daily dose should be taken as 30 divided doses, during 7 consecutive days.

Giardiasis
• Adults and children aged over 15: 0.750 g to 1 g/day.
• Children: from 2 to 5 years old: 250 mg/day, from 5 to 10 years old: 375 mg/day, from 10 to 15 years old: 500 mg/day.
For children, metronidazole oral solution or metronidazole 250 mg tablet is more suitable. The daily dose should be taken as a single dose or two divided doses, for 5 consecutive days.

Anaerobic infections
Adults: 1 g to 1.5 g/day.
Children: 20 to 30 mg/kg/day.

Method of administration
Oral use.

CONTRA-INDICATIONS
This medicinal product must not be used in the following cases:
• Known hypersensitivity (allergy) to metronidazole, to any of its excipients or to other medicinal products containing imidazole derivatives.
• In patients intolerant or allergic to gluten, due to the presence of wheat starch. This medicinal product should generally not be used in combination with disulfiram or alcohol.

In case of doubt you must consult your physician or pharmacist.

WARNINGS AND PRECAUTIONS
• Patients should be advised not to drink alcohol during treatment and for at least 24 hours...
needed due to increased bleeding potential), lithium and cyclosporine (monitor for signs of toxicity as the clearance may be reduced). Taking this medicinal product can disrupt the results of some laboratory tests (search for treponemes by TPI test).

In order to avoid possible interactions with other medical products, you must inform your physician or pharmacist about any other current treatment.

SIDE EFFECTS
Like any active substance, this medicinal product may induce, in some patients, undesirable effects to a greater or lesser degree.

The following undesirable effects may occur:

- digestive upsets: abdominal cramps, nausea, vomiting, diarrhea, oral mucositis (inflammation of the oral mucous membrane), taste disorders, loss of appetite, exceptional and reversible cases of pancreatitis (inflammation of the pancreas).
- allergic reactions: rash (eruption, pruritus (itching), flushing, urticaria (skin eruption with itching wheals), fever and angioedema (a severe condition characterized by the swelling of face, tongue, throat or larynx), exceptional anaphylactic shocks (a severe allergic reaction of sudden onset) and very rare pustular eruptions.
- peripheral and central nervous system disorders: peripheral sensory neuropathy, headache dizziness, convulsions and ataxia (involuntary movements).
- psychiatric disorders: psychotic disorders including confusion and hallucinations.
- visions disorders: transient vision disorders such as diplopia (perception of double vision) or myopia.
- hematology disorders: very rare cases of agranulocytosis (a decrease in blood count of certain white cells), neutropenia (decrease in the number of neutrophils, a type of white blood cells) and thrombocytopenia (decrease of the number of platelets) have been reported.

• liver: very rare cases of reversible abnormal liver function tests and cholestatic hepatitis have been reported. Do not hesitate to ask your physician or pharmacist for advice and to report any undesirable effect not mentioned in this leaflet.
OVERDOSAGE
In case of overdose, inform your physician immediately. There is no specific antidote. In case of overdose, a symptomatic treatment should be instituted.

STORAGE
Store between 15-25°C.

PRESENTATIONS
Tablets
NIDAZOLE 250: Metronidazole USP 250 mg/tablet
Excipients: Pregelatinized Starch, colloidal silicon dioxide, microcrystalline cellulose, magnesium stearate, talc, titanium dioxide, polyethylene glycol, hydroxypropylmethylcellulose, simethicone emulsion, carmellose sodium, FD & C Yellow No.6 Lake, polyacrylate dispersion 30%.

NIDAZOLE 500: Metronidazole USP 500 mg/tablet
Excipients: Povidone K 30, purified water, microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, talc, titanium dioxide, polyethylene glycol, simethicone emulsion, carmellose sodium, hydroxypropylmethylcellulose, quinoline yellow lake, polyacrylate dispersion 30%.

Suspension
NIDAZOLE 125: Metronidazole (as benzoate) 125 mg/5 ml
NIDAZOLE 200: Metronidazole (as benzoate) 200 mg/5 ml
Excipients: Xanthan gum, sorbitol, glycerin, sucrose, methyl paraben, propyl paraben, simethicone emulsion, sodium saccharin, tangerine liquid flavor, monoammonium glycyrrhizinate, purified water.