METAPHARMACEUTICAL

TECHNICAL DATA SHEET

1294-TDS-ENG-2026

METRONIDAZOL (EUR. PH.)		
DESCRIPTION DCI: METRONIDAZOLE		DESCRIPTION DOE: METRONIDAZOL
CAS Nº: 443-48-1	EC Nº: 207-136-1	AEMPS CODE: 1966A
MOL. WEIGHT: 171,20	MOL. FORMULA: C6H9N3O3	ARTICLE CODE: 1294

ATTRIBUTES	SHOULD BE
Appearance	White or yellowish, crystalline powder
Solubility	Slightly soluble in water, in acetone, in alcohol and in methylene chloride
Identification C	Complies
Appearance of solution	Not more opalescent than ref. susp. II and not more intensely coloured than ref. sol. GY6
Related substances	
Any impurity	=< 0.1 %
Total impurities	=< 0.2 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 12.1

STORAGE

Keep the container thightly closed. Store it in a cool and dry place.

REMARKS

Metronidazole is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents"

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses

METRONIDAZOLE is an active nitroimidazole antibiotic against protozoa, helminths, and anaerobic bacteria. It works by altering the DNA of the susceptible germs and preventing their synthesis.
METRONIDAZOLE is rapidly absorbed after oral administration with an approximate bioavailability of 100%. The rectal bioavailability is 60 - 80%, and vaginal route 20 - 25%. It is widely distributed in most tissues and fluids, including bile, saliva, bones, seminal fluid, vaginal secretions, breast milk, etc ... Most of it is excreted in urine, especially in the form of metabolites, and in a small amount in feces. It crosses the placental barrier and quickly passes into the fetal circulation. It binds a maximum of 20% to plasma proteins. It is metabolized in the liver by oxidation of the side chain and formation of the glucuronide. The elimination half-life is about 8 h.
It is active against Trichomonas vaginalis, Entamoeba histolytica, Giardia lamblia, Gardnerella vaginalis, Helicobacter pylori,

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Balantidium coli, Blastocystis hominis, Bacteroides, Clostridium, and some spirochetes.
It is indicated in:

Trichomoniasis: is an agent of choice in genital infections by trichomonas in men and women.
Non-specific vaginitis
Amebiasis: it is also an agent of choice for this pathology.
Balantidiasis
Giardiasis
Acute dental infections.
Acne rosacea.
Ulcers by decubitus.
Acute necrotizing ulcerative gingivitis or Vincent's infection.
Gastroduodenal ulcers: in combination with other drugs.
Anaerobic infections of the abdominal cavity.
Pseudomembranous colitis.
Perioral dermatitis.
Prophylaxis of some surgical infections.

It is administered orally (in capsules or tablets), rectally (suppositories), vaginally (ovules or vaginal tablets), and topically (gels or creams).
Orally, it can be administered with food or after meals.
Topically, it is incorporated into gels or emulsions with an O / W or W / O sign.

Dosage
Non-specific trichomoniasis and vaginitis: a single dose of 2 g orally, or 200-250 mg/8 h or 400-500 mg/12 h for 7 days. You can also administer 500 mg ovules for 20 days.
Amebiasis and balantidiasis: 400-800 mg/8 h orally for 5 - 10 days (in children normally 35 - 50 mg/kg /day in several doses).
Giardiasis and acute dental infections: 2 g/24 h orally for 3 days, or 400 mg/8 h for 5 days, or 500 mg/12 h for 7 - 10 days (in children normally 15 mg / Kg / day in several takes).
Acne rosacea: 200 mg/12 h orally and 0.75 - 2 % topically.
Decubitus ulcers: 400 mg / 8 h orally for 7 days, and also 1% via topical.
Acute necrotizing ulcerative gingivitis and dental infections: 200 mg/8 h orally for 3 days.
Gastroduodenal ulcers: 400 mg/8 - 12 h for 7 days.
Anaerobic infections: 800 mg initial oral followed by 400 mg/8 h for 7 days. Intravenous route 500 mg / 8 h.

Side effects
The adverse effects of METRONIDAZOLE are a function of the dose and the duration of the treatment. The most frequent are gastrointestinal disorders, especially nausea and metallic taste, which sometimes accompany headache, anorexia, and vomiting.
Likewise, diarrhea, constipation, dry mouth, tongue saburral, glossitis, and stomatitis can occur, being associated with cases of pseudomembranous colitis and pancreatitis. In addition, peripheral neuropathy may appear, usually with numbness and tingling of the extremities and epileptic seizures. Other symptoms in the CNS are weakness, dizziness, ataxia, drowsiness, insomnia, depression, or confusion. Moderate transient leukopenia, skin rashes and pruritus, and anaphylactic reactions may occur. Other side effects include urethral disorders and darkening of urine, as well as elevations in liver enzymes. Intravenously, it can cause thrombophlebitis.

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Vaginal urethral burning, vaginal itching, vaginitis, urinary continence, and cystitis. It can stain the urine red or brown, although this has no pathological significance.

Contraindications
Diseases of the central nervous system.
Avoid administration during pregnancy (especially in the first trimester) and during breastfeeding.

Precautions
Contraindicated in allergy to nitroimidazoles.
It should be used with caution in patients with blood dyscrasias or CNS disorders.
When therapy exceeds 10 days, treatment should be discontinued if signs of peripheral neuropathy or CNS toxicity appear.
Reduce dose in patients with severe liver disease. Rectally, METRONIDAZOLE is absorbed more slowly and therefore suppositories are not recommended in case of serious infections.
During the treatment, drinking alcohol should be avoided since antabuse reaction may occur.

Interactions
The simultaneous use of METHRONIDAZOLE and disulfiram can cause acute psychosis or mental confusion.
Reactions have been described when administered with pharmaceutical preparations containing alcohol.
It can potentiate the effect and toxicity of oral anticoagulants, phenytoin, lithium, and 5-fluorouracil, while its action and toxicity can be increased by cimetidine and reduced by barbiturates.

Other observations
It is thermolabile and photosensitive.

Compounding examples

METRONIDAZOLE Gel
METRONIDAZOLE - **0.75 %**
Neutral gel c.s.p. - **50 g**

Modus operandi: Prepare the neutral gel, for example Carbopol. In a mortar, crush and moisten the METRONIDAZOLE with a little propylene glycol, and incorporate the gel, homogenizing well.

METRONIDAZOLE cream
METRONIDAZOLE - **2 %**
Emulsion O / W c.s.p. - **100 g**

Modus operandi: The O / W emulsion can be prepared, for example, with Base O / W 1011. In a mortar, grind and moisten the METRONIDAZOLE with a little propylene glycol, and incorporate the base, homogenizing well.

METRONIDAZOLE capsules
METRONIDAZOLE - **250 mg**
for **1 capsule**, **No. 90**

Modus operandi: No. 2 capsules may be used, without the need for excipients.

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