PHOSVIT® / METRONIDAZOLE

Oral Suspensions, Tablets

Forms and Presentation

Phosvit® Oral Suspension: Bottle of 120 ml.

Metronidazole 250 mg: Packs of 20 tablets and 1000 tablets.

Composition

Phosvit® Oral Suspension: Each 5 ml contains Metronidazole 125 mg (in the form of Metronidazole benzoate).

Metronidazole 250 mg: Each tablet contains Metronidazole 250 mg.
Lactose, Microcrystalline Cellulose, Polyvinylpyrrolidone K30, and other excipients.

Properties

Metronidazole is an anti-infective agent which is active in some protozoal diseases and in bacterial infections caused by obligate anaerobic organisms. Its action is bactericidal. **Metronidazole** possesses a direct trichomonacidal and amebicidal action against *T. Vaginalis* and *Entameba histolytica*.

Indications

Metronidazole is largely indicated for the treatment of infections in which anaerobic bacteria have been identified or are suspected as pathogens especially *B. fragilis*, Fusobacteria, Eubacterials, Clostridia, and other cocci growing under the exclusion of air.

Metronidazole can be used in the treatment of infections of the gastrointestinal tract, after surgery of the colon, in peritoneal inflammations (peritonitis), in purulent diseases of the pelvic cavity (abscesses, phlegmons), in infections of the female genital tract (e.g. after hysterectomy and other gynecological surgery), as well as in puerperal fever.

Metronidazole is also applied in cases of sepsis, especially when it radiates from the gastrointestinal tract or the female genital tract, as well as in pneumonia, with histolysis (necrotising pneumonia), brain abscesses, osteomyelitis, and endocarditis. It can be used as a prevention of postoperative infections where contamination by anaerobic bacteria is to be expected.

Dosage and Administration

Amoebiasis

Adults : 1.5 g daily in 3 administrations.

Children: 30 - 40 mg / kg / day in 3 administrations.
Duration of treatment is 7 consecutive days. The treatment of the suppurative phase of hepatic amoebiasis must be associated with the removal of pus from the abscesses.

Trichomonal infestations

In women (trichomonal urethritis and vaginitis), a single dose of 2 g or a mixed treatment is given preferably with: daily administration of 2 tablets 250 mg by the oral route (one in the morning, one in the evening, during meals) for 10 consecutive days; insertion of 1 ovule into the vagina, every night for 10 days. The partner, whether he shows signs of clinical *T. vaginalis* infestation or not, must be treated even if there are no positive results in the laboratory tests.

In men (trichomonal urethritis): The daily dosage is a single dose of 2 g or 500 mg in 2 administrations by the oral route (one tablet in the morning and one in the evening, during meals) for 10 consecutive days. Very rarely, it may be necessary to increase the daily dosage to 750 mg.

Lambliasis

Adults: 3-4 tablets / day for 5 consecutive days.

Children from 2-5 years: 250 mg / day (1 tablet or 2 teaspoonfuls of oral suspension).

Children from 5-10 years : 375 mg / day (1 ½ tablets or 3 teaspoonfuls of oral suspension).

Children from 10-15 years: 500 mg / day (2 tablets or 4 teaspoonfuls of oral suspension).

Non-specific vaginitis: 500 mg for 7 days twice daily. The partner must be treated concurrently. In women, it would be beneficial to complete the oral treatment by a daily local insertion of 1 ovule.

Anaerobic infection

Adults: 1-1.5 g / day.
Children: 20-30 mg / kg BW / day.

Contraindications

This medicament is contraindicated in patients with known hypersensitivity to metronidazole, or to other

drugs formulated with imidazole derivatives. Also, metronidazole is contraindicated in cases of acute central nervous disease, diseases of the hemopoietic system, first trimester of pregnancy and lactation.

Precautions

- If **Metronidazole** should be administered longer than the usually recommended duration, hematological tests, especially white blood cell count, should be carried out. The occurrence of central or peripheral nervous system symptoms (convulsions, ataxias, paresthesias) should prompt drug withdrawal.
- Treatment should also be discontinued in the presence of severe leukopenia.
- While taking **Metronidazole**, patients should avoid all alcoholic beverages. In patients on alimentary regimens with oral or parenteral solutions, care should be taken to avoid ethanolic solutions.
- Patients on oral anticoagulation with warfarin, receiving metronidazole, need readjustment of the warfarin dose and careful monitoring.
- Pregnancy and lactation: **Metronidazole** should never be used in the first trimester of pregnancy. Administration during the second and third trimesters should be confined to vital indications. **Metronidazole** is known to pass into breast milk. It should, therefore, not be administered during breast feeding.

Drug Interactions

- Alcohol consumption may produce disulfiram-like manifestations with nausea, vomiting, flushes and blood pressure loss. Alcoholic beverages have been reported to have a different taste.
- On account of the cytotoxicity and teratogenicity of acetic aldehyde, alcohol consumption by pregnant women on metronidazole may cause fetal alcoholic syndrome.
- The combined use of metronidazole and disulfiram may produce psychotic symptoms.
- The combined use of metronidazole and aztreonam reduces peak aztreonam and metronidazole serum levels by roughly 10%.

Effects on diagnostic parameters:

- *Urine:* **Metronidazole** metabolites may cause reddish-brown discoloration of urine.
- *Plasma lipids:* Plasma lipids, particularly cholesterol levels may be reduced during metronidazole treatment.
- *Liver function parameters:* **Metronidazole** interferes with 2- stage serum glutamic oxaloacetic transaminase (serum aspartic aminotransferase) enzyme assays so that measured levels are lower than those actually present.

Side Effects

- The gastrointestinal side effects are the most common. They include loss of appetite, nausea, vomiting and occasionally diarrhea or constipation. Exceptionally, epigastric pain or abdominal cramps may also occur.
- Central nervous symptoms: Vertigo, ataxia, confusion, depression, convulsions, headache, fatigue as well as peripheral, mostly sensory neuropathies are rare and only occur after prolonged high-dose treatment.
- Unpleasant burning metallic taste;
- Glossitis and stomatitis sometimes associated with *C. albicans* overgrowth;
- Reversible neutropenia;
- Hypersensitivity reactions;
- Dark, brownish-red discoloration of urine attributable to the elimination of metabolites.

Storage

- Store in a cool and dry place, below 25°C.
- Keep out of the reach of children.
- Store away from heat and direct light.
- Shake well **Phosvit® oral suspension** before use.

Shelf Life: 3 years.

THIS IS A MEDICINE

- Medicines are products which affect your health, and failure to follow the instructions may be dangerous for you.
- Follow your doctor's advice carefully, the method of use, and the instructions of the pharmacist who sold you the medicine.
- Your doctor and pharmacist are expert in the use of medicines, and their benefits and risks.
- Do not stop your course of treatment early unless advised to do so by your doctor or pharmacist.
- Do not repeat the same prescription without consulting your doctor.

KEEP MEDICINES OUT OF THE REACH OF CHILDREN

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PHARMADEX S.A.L.
KAHALE - LEBANON