APPROVED
Order of Ministry of
Healthcare of Ukraine
11.05.2023 No. 879
Registration certificate
No. UA/16969/01/01

INSTRUCTION
for medical use

SAMITOL®

Composition:
active substance: secnidazole;
1 film-coated tablet contains 500 mg of secnidazole;
excipients: microcrystalline cellulose, colloidal silicon dioxide anhydrous, sodium starch glycolate (type A), magnesium stearate, hypromellose, polyethylene glycol.

Pharmaceutical form. Film-coated tablet.
Main physical and chemical properties: round, biconvex tablets, smooth on both sides, with film coating of white to off-white color.

Pharmacotherapeutic group. Antiprotozoals. Nitroimidazole derivatives.
ATC code P01A B07.

Pharmacological properties.
Pharmacodynamics.
Mechanism of action.
Secnidazole is an antiprotozoal agent of the nitroimidazole group with antibacterial activity. Secnidazole is characterized by bactericidal (against gram-positive and gram-negative anaerobic bacteria) and amebicidal (intra- and external) effect. Secnidazole is particularly active against *Trichomonas vaginalis*, *Entamoeba histolytica*, *Giardia lamblia*. Penetrating inside the cell of the microorganism, secnidazole is activated as a result of the 5-nitrogroup restoration, due to which it interacts with the cellular DNA. There is a violation of its spiral-like structure and the destruction of threads, inhibition of nucleotide synthesis and cell death.
Pharmacokinetics.
Absorption.
After oral administration, secnidazole is rapidly and completely absorbed from the gastrointestinal tract. Bioavailability is almost 100%. After oral administration of a 2 g single dose, peak secnidazole levels in serum are achieved within 3 hours.
Distribution.
The binding of secnidazole to plasma proteins is approximately 15%. Secnidazole passes through the blood-brain barrier, penetrates into breast milk.
Metabolism.
The secnidazole is metabolized predominantly in the liver.
Elimination.
The half-life of the secnidazole is approximately 25 hours. Secnidazole is excreted predominantly with urine. The elimination is slow: 16% of the administered dose of secnidazole is excreted within 72 hours and 50% within 120 hours.

Clinical characteristics.

Indication.

- Trichomonas urethritis and vaginitis (caused by *Trichomonas vaginalis*);
- bacterial vaginosis;
- amebiasis of the intestine (caused by *Entamoeba histolytica*);
- amebiasis of the liver (caused by *Entamoeba histolytica*);
- lambliasis (caused by *Giardia lamblia*).

Contraindication.

- Hypersensitivity to secnidazole or to other components of the drug or to other nitroimidazole derivatives;
- organic diseases of the central nervous system (CNS);
- 1st trimester of pregnancy;
- blood dyscrasia, including in the anamnesis.

Drug interactions and other types of interaction.

Disulfiram: a concomitant use of secnidazole can lead to paranoid reactions and psychosis.

Alcohol: combination with alcohol causes symptoms of a disulfiram-like reaction (abdominal cramping, nausea, vomiting, headache, blood flow to the face), delirious seizures and dizziness may develop.

Anticoagulants: secnidazole, when used simultaneously, enhances the effect of indirect anticoagulants (coumarin and indandione derivatives), and increases the risk of bleeding. Monitoring of prothrombin time and dose adjustment (if necessary) is required.

Preparations of lithium: when used concurrently with secnidazole, the concentration of lithium in blood plasma increases.

Cyclosporine: there is a risk of elevated serum cyclosporine levels. Monitoring of cyclosporine and creatinine levels should be performed in case of secnidazole and cyclosporine co-administration.

Non-depolarizing skeletal muscle relaxants (vecuronium bromide): it is not recommended to combine with secnidazole.

Amoxicillin: when used concurrently with secnidazole, activity against *Helicobacter pylori* increases (amoxicillin inhibits the resistance development).

5-fluorouracil: when used concurrently with secnidazole, the clearance of 5-fluorouracil decreases, causing an increase in its toxicity.

Special warnings.

Alcohol

During the use of the drug and within 72 hours after its end, alcohol use is contraindicated in order to prevent the occurrence of adverse reactions similar to those observed with the use of disulfiram (redness of the skin, colicky abdominal pain, vomiting, and tachycardia).

Long-term use

If it is necessary to use secnidazole for a longer period than recommended, patients should monitor the blood picture (in particular, the number of leukocytes). Also, a doctor's supervision is recommended due to the risk of side effects of the central nervous system and the peripheral nervous system (paresthesia, ataxia, dizziness, convulsive attacks).

Hepatic encephalopathy

Secnidazole should be prescribed with caution in patients with hepatic encephalopathy. Therapy should be stopped in the event of motor dysfunction, dizziness, or obscuration of consciousness.

Sexual relationships

You must refrain from sexual intercourse during secnidazole therapy.

Administration during pregnancy and lactation.
Do not use the drug during pregnancy or lactation.

Influence on ability to drive car or operating machinery.
Secnidazole does not influence the ability to drive car or operating machinery.

Administration and dosage.
Samitol® should be used orally just before meal, with a small amount of water.
Doses for adults
Urogenital trichomoniasis, bacterial vaginosis: 4 tablets of 500 mg to be taken once a day or twice a day at an interval of 12 hours (total 2 g).
Acute intestinal amebiasis and giardiasis: 4 tablets of 500 mg to be taken once a day or twice a day at an interval of 12 hours (total 2 g).
Chronic carriage of cysts or amoeba: 3 tablets of 500 mg to be taken once or in several doses for 3 days.
Liver amebiasis: 3 tablets of 500 mg to be taken once or in several doses for 5 days.
Doses for children*
At the discretion of the doctor, 25 to 30 mg/kg/day. The duration of treatment depends on the indication and is similar to that for adults.
* This pharmaceutical form is intended for use by children with a body weight of over 20 kg.
Doses for patients with renal or hepatic insufficiency
For patients with renal or hepatic insufficiency, recommendations for adjusting doses depend on those recommended for nitro-5-imidazole derivatives in general.
Moderate-to-severe renal insufficiency: usually dose adjustments are not required, especially with short-term treatment.
Severe hepatic insufficiency: a reduction in the daily dose is necessary depending on the patient's condition.

Children.
The drug is authorized for use by children in accordance with the dosage recommendations given in the "Administration and dosage" section, taking into account the possibility of using this dosage form for children with a body weight of more than 20 kg.

Overdose.
Symptoms: possible increase in side effects, particularly of the nervous system.
Treatment: there is no specific antidote. If necessary, symptomatic therapy or hemodialysis should be used.

Adverse reactions.
Immune system disorders: hypersensitivity reactions, including hyperemia (erythema), rash, urticaria, angioedema, bronchospasm, fever, and anaphylactic reactions.
Blood and lymphatic system disorders: moderate reversible leukopenia, reversible neutropenia, agranulocytosis, thrombocytopenia.
Cardiovascular system disorders: palpitations.
Gastrointestinal tract disorders: pain in the epigastric area and/or in the abdominal cavity, nausea, vomiting, diarrhea, constipation, glossitis, stomatitis, taste disturbance (metallic taste in the mouth), anorexia.
Hepatobiliary disorders: hepatitis.

Nervous system disorders: headache, convulsions, dizziness, loss of consciousness, paresthesia, neuropathy (sensory peripheral and sensory-motor polyneuritis), encephalopathy* (obscuration of consciousness), cerebellar syndrome* (ataxia, dysarthria, motor dysfunction, nystagmus, tremor).
Mental disorders: psychosis, confused consciousness, hallucinations.
General disorders: general weakness.
Note: * after discontinuation of treatment the symptoms disappear.
Reporting of suspected adverse reactions.
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Medical and pharmaceutical workers, as well as patients or their legal representatives are asked to report any suspected adverse reactions and lack of effectiveness of the medicinal product through the Pharmacovigilance Automated Information System at: https://aisf.dec.gov.ua.

Shelf life.
3 years.

Storage conditions.
Store in original package at a temperature not more than 25°C.
Keep out of reach of children.

Package.
4 tablets in blister; 1 blister in cardboard packaging.

Conditions of supply.
By prescription.

Manufacturer.
KUSUM HEALTHCARE PVT LTD.

Location of manufacturer and its address of business activity.
SP-289 (A), RIICO Industrial area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan), India.

Date of last revision.
05.04.2024