FEMIBEST
Instructions
on medical use of the drug

Trade name: Femibest.
INN: Metronidazole + neomycin sulfate + nystatin + dexamethasone + lidocaine.
Dosage form: Vaginal suppositories.
Pharmacotherapeutic form: Antiseptics and antimicrobials for the treatment of gynecological diseases in combination with corticosteroids. Combined agent (antimicrobial, antiprotozoal, antifungal agent).
Composition: *Each suppository contains:*
Metronidazole …. ……..... ..500 mg;
Nystatin …. ……..100,000 IU;
Neomycin sulfate…. . ..... …….....5 mg;
Dexamethasone .... ……..0.2 mg;
Lidocaine .....10 mg;
Excipients ..... . ……qs.
Pharmacological properties:
Pharmacodynamics:
Combined drug for local use in gynecology. A drug with antibacterial, antiprotozoal , antifungal and anti-inflammatory, antiexudative effects. Reduces the formation, release and activity of inflammatory mediators (histamine, kinin, prostaglandins, lysosomal enzymes). Suppresses cell migration to the site of inflammation, reduces vasodilation and increased vascular permeability at the site of inflammation. Reduces exudation due to vasoconstrictor action. Helps quickly reduce burning and itching.
Metronidazole belongs to 5-nitroimidazoles and is a drug with a bactericidal type of action, exhibiting tropism for DNA. The mechanism of action of metronidazole is the biochemical reduction of the 5-nitro group of metronidazole by intracellular transport proteins of anaerobic microorganisms and protozoa. The reduced 5-nitro group of metronidazole interacts with the DNA of microbial cells, inhibiting the synthesis of their nucleic acids, which leads to the death of microorganisms. Metronidazole is an effective antimicrobial and antiprotozoal agent with a broad spectrum of action. The drug exhibits high activity against: Trichomonas vaginalis, Entamoeba histolytica, as well as in relation to Granaerobes Bacteroides spp. (including B. fragilis, B. ovatus, B. distasonis, B. thetaiotaomicron, B. vulgatus), Fusobacterium spp. and some gram-positive anaerobes (susceptible strains of Eubacterium spp., Clostridium spp., Peptostreptococcus spp., Peptococcus spp.).
To metronidazole, but in the presence of mixed flora (aerobes and anaerobes), metronidazole acts synergistically with antibiotics that are effective against common aerobes.
Neomycin - a broad-spectrum antibiotic from the group of aminoglycosides . Acts bactericidal against gram-positive (Staphylococcus, Streptococcus pneumoniae) and gram-negative (Escherichia coli, Shigella dysenteriae, Shigella flexneri, Shigella boydii, Shigella sonnei, Proteus spp.) microorganisms. Microbial resistance develops slowly and to a small extent. The mechanism of the bactericidal action of neomycin is associated with the effect on ribosomes and inhibition of protein synthesis in the bacterial cell. Inactive against Streptococcus spp. Resistance of microorganisms to neomycin develops slowly and to a small extent.
Nystatin is an antifungal antibiotic from the group of polyenes , highly effective against yeast-like fungi of the genus Candida, binding to sterols in the cell membrane, disrupting its permeability and slowing down their growth, leading to the death of fungi. Has a fungicidal effect on pathogenic fungi, especially yeast-like ones of the genus Candida albicans, Cryptococcus, Hystoplasma. Improves trophic processes in the mucous membrane.
Lidocaine stabilizes the neuronal membrane by inhibiting the ionic currents necessary for the initiation and conduction of impulses, thereby exerting a local anesthetic effect.
Dexamethasone is a hydrocorticosteroid that has pronounced local anti-inflammatory activity.
Pharmacokinetics:
Metronidazole is evenly distributed throughout the vaginal mucosa, providing a local bactericidal effect. Bioavailability metronidazole with intravaginal administration is 20%. Passes through the blood-brain and placental barrier, penetrates into breast milk. The drug is metabolized in the liver. The half-life of metronidazole is 6-11 hours. It is excreted by the kidneys (about 20% unchanged) and intestines.
Neomycin – does not penetrate into the blood through the mucous membranes of the genital organs.
Nystatin when applied topically, it is practically not absorbed through the mucous membranes.
Lidocaine - action begins within 3-5 minutes. Lidocaine is absorbed when applied superficially to damaged skin and mucous membranes and is quickly metabolized in the liver. Metabolites and the drug unchanged (10% of the administered dose) are excreted through the kidneys. After daily intravaginal administration for 3 days, lidocaine is absorbed in minimal quantities, and its plasma levels are 0.04-1 mcg/ml.
Dexamethasone: Although dexamethasone concentrations are low, a systemic effect cannot be ruled out in some patients. After absorption of the drug, dexamethasone binds to plasma proteins, is metabolized by the liver and excreted by the kidneys.
Indications for use:
- Vulvitis, vulvovaginitis, cervicovaginitis;
- Vaginal candidiasis caused by Candida albicans;
- Bacterial vaginosis caused by anaerobic bacteria and Gardnerella vaginalis;
- Trichomonas vaginitis caused by Trichomonas vaginalis;
- Vaginitis caused by mixed infections (Trichomonas, anaerobes, including Gardnerella vaginalis, yeast-like fungi);
- Preoperative prevention of infectious complications during gynecological interventions;
- Before and after diathermocoagulation of the cervix;
- Before intrauterine diagnostic procedures.

Mode of application:

Intravaginally, 1 vaginal suppository 1 time per day (in the evening before bedtime). The suppository is inserted daily deep into the vagina, in a lying position, before bedtime. The average duration of treatment is 6-12 days.
For trichomonas vaginitis, if necessary, local treatment is continued for another 10-12 days.
The drug is recommended to be prescribed after the end of menstruation. If menstruation begins during treatment, interrupting therapy is not recommended. You should use sanitary pads rather than tampons. During menstrual bleeding, the drug is administered intravaginally, according to the usual regimen.

Contraindications:

- hypersensitivity to the components of the drug;
- viral infection (Herpes simplex);
- patients who drink alcohol during treatment or within 3 days after the end of treatment;
- severe liver dysfunction;
- renal failure;
- childhood and adolescence;
- diseases of the hematopoietic system (leukemia, hematopoiesis disorders);
- pregnancy;
- period of breastfeeding.

Warning:

During treatment with the drug and at least one day after treatment, drinking alcohol is prohibited.
A drug should not be used in virgins or young girls who have not reached puberty.
Not used before sexual intercourse. During treatment, it is recommended to abstain from sexual intercourse.
When treating trichomonas vaginitis, simultaneous treatment of the sexual partner (metronidazole orally) is recommended due to the risk of re-infection. When prescribing the drug simultaneously with oral administration of metronidazole , especially during a repeated course of treatment, monitoring of the composition of peripheral blood is necessary (the possibility of developing leukopenia).

Precautions:

It is not recommended to use the drug for patients with Crohn's disease.
Metronidazole penetrates the placental barrier and quickly enters the fetal circulation. Fertility studies in rats at doses 5 times the recommended human dose showed no evidence of adverse effects on pregnancy or the fetus. No fetotoxicity was observed when administered orally to pregnant mice at a dose of 20 mg/kg/day, nearly 1.5 times the recommended human dose (750 mg/day). Moreover, there have been no well-controlled studies in pregnant women. Since the results of animal studies do not always coincide with the results in humans, metronidazole is used during pregnancy only if clearly necessary.
Patients should refrain from drinking alcoholic beverages or other drugs containing alcohol (elixir, tonic, syrup) during treatment with metronidazole; alcohol can be consumed 1 day after completion of treatment, as this affects the metabolism of alcohol.

Pregnancy and lactation:

Metronidazole is excreted into breast milk in concentrations similar to those achieved in plasma after oral administration. It is necessary to evaluate the benefit-risk ratio before prescribing metronidazole during lactation. Not recommended for use during pregnancy.

Drug interactions:

- enhancing the effects of oral anticoagulants (such as warfarin);
- phenytoin and phenobarbital reduce the half-life of metronidazole;
- enzyme inhibitors, such as cimetidine, inhibit the hepatic metabolism of metronidazole and increase the half-life;
- when administered simultaneously with lithium, metronidazole increases serum concentrations, which can cause intoxication;
- alcohol and disulfiram with metronidazole can provoke symptoms of nausea, headache, flushing;
- it is not recommended to use nystatin and neomycin in parallel with spermicide.

Effect on laboratory test results:

Metronidazole may affect serum levels of aspartaminotransferase (AST, SGOT), alanine aminotransferase (ALT, SGPT), lactate dehydrogenase (LDH), triglycerides and glucose hexogenase.

Side effects:

Sometimes cases of local irritation are possible. The most frequently reported side effects are gastrointestinal disorders (nausea, abdominal pain, diarrhea, etc.). Other less common side effects include a metallic taste in the mouth and changes in the tongue and oral mucosa, reversible leukopenia, peripheral neuropathy, dizziness, ataxia, confusion , irritability, depression, weakness and insomnia.
In sensitive patients, side effects such as allergic reactions, such as urticaria, rash, flushing, nasal congestion, dry mouth, vulva and vagina, and fever, have been noted. In extremely rare cases, dysuria, cystitis, urinary incontinence and a feeling of bladder fullness, dark urine, dyspareunia, decreased libido, proctitis, joint pain and pancreatitis have been noted.

Overdose:

In case of overdose, contact the nearest medical facility.

Release form:

6 vaginal suppositories along with instructions for medical use are placed in a cardboard package.

Storage conditions:

Store in a dry and dark place at a temperature not exceeding 25 °C.

Keep out of the reach of children.
Conditions for dispensing from pharmacies:
By doctor's prescription

Made for:

MAXX PHARM LTD.

London, Great Britain