INSTRUCTION
for medical use of medicinal product

PROTEFLAZID
(PROTEFLAZIDUM)

Composition:

active ingredient: 1 suppository contains Proteflazid flavonoids derived from the mixture of herbals (1:1) of Tufted hair grass (Herba *Deschampsia caespitosa* L.) and Bush grass (Herba *Calamagrostis epigeios* L.) not less than 1,8 mg;
excipients: butylhydroxyanisole (E 320), polyethylenglycol-400, polyethylenglycol-1500, polyethylenglycol-4000, until the mass 3g is received.

Dosage form. Suppositories.
Main physical and chemical properties: grey-green torpedo-shape suppositories.

Pharmacotherapeutic group:
Direct-acting antiviral drugs Code ATC J05A X.
Other gynecological drugs. Code ATC G02C X.

Pharmacological properties
Pharmacodynamics.
The active ingredient of the drug (flavonoids) inhibits synthesis of DNA- and RNA-viruses in the infected cells through the inhibition of activity of virus-specific enzymes RNA-, DNA-polymerases, thymidine kinase and reverse transcriptase, possesses immunotropic properties.
It has been established that the active ingredient facilitates synthesis of endogenous α- and γ-interferons to physiologically active level (without refractoriness) increasing local non-specific resistance to viral and bacterial infections.
Clinical studies have shown that Proteflazid (suppositories) restores the protective function of mucous membrane of the vagina and cervix uteri normalizing the parameters of local immunity (sIgA; lysozyme and complement component C_3).
Studies in experimental models of oncogenic human papilloma viruses in vitro proved that the active ingredient of the drug has a specific antiviral activity and inhibits reproduction of human papillomavirus on 2 Ig ID_{50}.
Cytological studies have established that the active substance inhibits proliferative and destructive impact of Human papillomavirus over cells.
During the treatment of epithelial dysplasia of cervix caused by papillomavirus infection, the normalization of a cytogram or transition from cervical intraepithelial neoplasia class CIN-II (Moderate dysplasia) to class CIN-I (mild dysplasia) has been registered.
In the case of genital herpes, the drug prevents formation of new elements of rash, decreases the likelihood of dissemination and visceral complications and fastens regenerative processes.
In the case of vaginosis, vaginitis and inflammatory diseases of cervix uteri, the drug facilitates the local immune reconstitution and quicker and more effective elimination of the pathogen.
The drug facilitates the elimination of dysbiotic disorders of genital tract microflora, reconstructs normal vaginal biotope, accelerates processes of reconstruction of epithelium of endocervix; prevents recurrences of the diseases.
The drug possesses antioxidant activity, which inhibits free-radical processes, thus preventing accumulation of lipid peroxidation products, enhances anti-oxidant status of cells.

The drug is an apoptosis modulator, which intensifies the effect of apoptosis-inducing factors, activating caspase 9, resulting in quicker elimination of virus infected cells and primary prevention of chronic diseases on the background of latent viral infections.

Pharmacokinetics.

The active ingredient does not penetrate into general circulation and has no systemic exposure, when applied topically. The investigations proved that by vaginal use the therapeutic concentration of the drug is reached locally.

Clinical characteristics.

Indications.

Treatment of diseases of female genital organs caused by:

- herpes simplex virus types I and II, cytomegalovirus and Epstein-Barr virus;
- human papillomavirus, including oncogenic strains.

As a part of comprehensive treatment of female genital diseases caused by:

- pathogens of inflammatory diseases of mixed etiology (viruses, bacteria, pathogenic fungi, chlamydia, mycoplasma, ureaplasma).

Contraindications.

Individual hypersensitivity to the drug ingredients.

Special safety precautions.

Do not use suppositories orally.

The drug does not require any special precautions.

Interaction with other drugs and other kinds of interactions.

Proteflazid (suppositories) can be combined with other antiviral drugs and antibiotics for the treatment of viro-bacterial and viro-fungal diseases of pelvic organs. No negative manifestations associated with interaction with other drugs have been found.

In the event of any adverse reaction caused by combined use of the drug, consult a doctor.

Peculiarities of use.

It is recommended to avoid sex intercourse during the treatment by the suppositories.

Etiopathogenetical therapy of diseases specified in section “Indications”, except local therapy with Proteflazid (suppositories), should be supplemented with oral use of Proteflazid (drops) according to the schemes and at the dosage specified in the respective instruction.

To reach a desirable therapeutic effect in the treatment of genital diseases caused by pathogens of viral, bacterial, fungal infections and their associations (chlamydia, mycoplasma, ureaplasma) simultaneous treatment of both sexual partners is necessary.

In this case, Proteflazid (drops) should be used for treatment of a partner according to the schemes and the dosage specified in the respective instruction.

Use during pregnancy or breastfeeding.

Pre-clinical studies of the active ingredient of Proteflazid extract have revealed no toxicological, teratogenic, mutagenic, embryotoxic, fetotoxic and oncogenic effects. Clinical experience of the use of Proteflazid (drops) in I-III trimesters of pregnancy and lactation did not reveal any negative impact.

It is necessary to follow the drug prescribing rules during pregnancy or breastfeeding, by evaluating the risk-benefit ratio. The drug should be administered and used only under medical

supervision.
Influence on the ability to operate a vehicle or other mechanisms.
No negative influence over potentially hazardous activities that require special attention and quick reaction has been revealed.

Dosage and Administration
Suppositories shall be used vaginally.
The suppositories shall be used after hygienic procedures. It is necessary to remove the protective plastic packaging before the use of suppositories. Suppository should be inserted deeply into vagina. It is recommended to stay in a lying position for at least 3 hours and to avoid sexual intercourse minimum for 8 hours, after inserting the suppository.
It is recommended to start treatment immediately after menstruation. It is necessary to interrupt the treatment during menstruation period.
To treat genital diseases caused by herpes viruses types I and II, use 1 suppository once a day for 7-10 days and more until the symptoms disappear.
To treat recurrent herpes infections, including the presence of cytomegalovirus infection or Epstein-Barr infections, use 1 suppository once a day for 10 days. Course of treatment is 3 months (10 days per month).
In case of papillomavirus infection and/or herpetic infection in combination with bacterial and fungal infections use 1 suppository twice a day for 14 days. Course of treatment lasts 3 months (14 days per month).
Children.
The use of Proteflazid in suppositories in children has not been studied; the drug should not be administered to children.

Overdose.
Cases of overdosage are unknown. In case of overdose, it is necessary to seek medical attention straight away and ask an advice for further treatment.
Adverse reactions.
The use of the drug can cause mild local itching or mucous membrance irritation, that usually disappear spontaneously and do not require discontinuation of therapy.
Hypersensitivity reactions, allergic reactions are possible.
In case of allergic reactions or any other undesirable reactions stop using suppositories and consult a doctor for further therapeutic approach.

Shelf-life.
2 years.

Storage conditions.
Store in the original package out of reach of children at temperature not above 25°C.
Do not freeze!

Package.
5 suppositories in a blister, 2 blisters in a pack.

Category of prescription.
By prescription.

Manufactured by:
«Pharmex Group» LLC.,
100 Shevchenka Str., Boryspil, Kyiv Region, 08300, Ukraine

Under Authorisation from:
"Scientific & Manufacturing Company "Ecopharm" LTD.,
9-V Stepana Bandery Av., Kyiv, 04073, Ukraine.

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