INSTRUCTION
formedical use of medicinal product
FLAVOVIR®
(FLAVOVIR®)

Composition:
1 ml of syrup contains:
0,02 ml of liquid extract Proteflazid obtained from the mixture of herbals (1:1) tufted hair grass (Herba *Deschampsia caespitosa* L.) and bush grass (Herba *Calamagrostis epigeios* L.) (extraction solvent – ethanol 96 %), which is the equivalent of not less than 0,0035 mg of flavonoids in terms of rutin;
Excipients: propylene glycol, ethanol 96 %, sorbite (E 420), methylparaben (E 218), propylparaben (E 216), sodium sulphite (E 221), purified water.

Dosage form. Syrup.
Main physical and chemical properties: Transparent sweet yellow-greenish liquid with a faint specific smell.

Pharmacotherapeutic group.
Direct-acting antiviral drugs Code ATX J05A X.
Immune stimulants. Code ATX L03A X.

Pharmacological properties
Pharmacodynamics.
Flavonoids which compose the drug are capable of inhibiting replication of DNA- and RNA-viruses both in vitro and in vivo. Inhibitory activity of the drug towards influenza virus and acute viral respiratory infections (A.V.R.I.), herpes viruses has been revealed in pre-clinical and clinical studies.
It has been established that the mechanism of direct antiviral action includes the inhibition of synthesis of virus specific enzymes – DNA- and RNA-polymerases, thymidine kinase, reverse transcriptase, neuraminidase and induction of synthesis of endogenous interferon.
The drug protects mucous of upper respiratory tracts, normalizing the local immunity parameters (lactoferrin, sIgA and lysozyme).
During the studies it has been established that the drug normalizes synthesis of endogenous α- and γ-interferons to physically active level, increasing organism's non-specific resistance to viral and bacterial infections.
Clinical studies showed that the daily administration of the drug according to the age-specific dosage and regimen does not induce immune system's refractoriness, and inhibition of the synthesis of α- and γ- interferons.
Mentioned ability of Flavovir® syrup maintains the interferon level sufficient for an adequate immune response of an organism against infectious agent. In turn, this enables patients to use the drug for a long time, if necessary.
The drug possesses antioxidant activity, which inhibits free radical processes. Thus it prevents accumulation of lipid peroxidation products, enhances anti-oxidant status of cells, diminishes intoxication, facilitates recovery after illness and adaptation to adverse environmental conditions.
The drug is an apoptosis modulator which intensifies the activity of apoptosis-inducing factors, specifically: activates caspase 9, resulting in quicker elimination of cells affected by virus and primary prevention of chronic diseases on the background of latent viral infections.

Pharmacokineticks.
Active ingredients of the drug are quickly absorbed from gastrointestinal tract into bloodstream, reaching maximum concentrations within 20 minutes after administration (investigation *in vivo*). Taking into account existing dynamics, plasma elimination half-life is approximately 2.3 hours. Bioavailability at oral administration makes 80%. Elimination is slow. The level of accumulation of active ingredients in blood cells is much higher in comparison to blood plasma. Corresponding concentrations of active ingredients prolong the action of the drug in a human body and accumulation in organs and tissues as a result of their release from blood cells. Such pharmacokinetic changes of accumulation and release of active ingredients from blood cells determine requirement to take the drug twice a day to reach the effective concentrations.

Clinical characteristics
Indications.
- Etiotropic treatment and prevention of ARVI;
- Etiotropic treatment and prevention of influenza, including influenza caused by viruses of pandemic strains.

Contraindications.
Hypersensitivity to the drug ingredients. Stomach ulcer or duodenal ulcer in acute stage. Autoimmune diseases.
Interaction with other drugs and other kinds of interactions.
During clinical use it was established that syrup Flavovir® can be combined with antibiotics and antifungal drugs for treatment of viro-bacterial and viro-fungal diseases. No negative manifestations associated with interaction of syrup Immunoflazid® with other drugs have been found.
Administration details.
Patients with chronic gastroduodenitis in case of recrudescence of gastroduodenitis or esophageal reflux should take syrup in 1,5-2 hours after meal.

Use during pregnancy or breastfeeding.
Pre-clinical studies didn`t reveal any teratogenic, mutagenic, embryotoxic, fetotoxical and oncogenic influences. Clinical experience of use of the drug in I-III trimesters of pregnancy and lactation didn't reveal any negative influence. Nevertheless, it is necessary to observe the rules of prescription of drugs during pregnancy or breastfeeding, estimating benefit-risk profile and consult a doctor.

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
Shake the vial with syrup before use.
The syrup should be dosed using dosing capacity and taken orally 20-30 minutes before meal. To increase therapeutic effect in case of respiratory viruses it is recommended to keep the syrup for 20-30 seconds in the mouth, gargling before swallowing.
Dosage and duration of treatment depend on type of disease and age of a patient.

Dosage (ml) and dosage frequency

Age of a patient (in years)	Dosage (ml) and dosage frequency
Since birth to 1 year	0,5 ml twice a day
From 1 to 2 years	1 ml twice a day
From 2 to 4 years	3 ml twice a day
From 4 to 6 years	4 ml twice a day
From 6 to 9 years	5 ml twice a day
From 9 to 12 years	6 ml twice a day
From 12 years and adults	9 ml twice a day

The syrup should be used for 5 days for treatment of influenza and ARVI (without complications). To increase the efficiency of the therapy use syrup at the first manifestations of a disease or after a contact with patients. The treatment may be prolonged for 2 weeks, depending on the course of the disease.
For prevention of influenza and ARVI half of the curative dose of the syrup should be used for 1-4 weeks.
The term of using the syrup for prophylaxis can be extended to 6 weeks during epidemic of pandemic strains.
To normalize the immune system in case of bacterial complications of influenza and other ARVI the syrup should be used for 4 weeks and longer.
Children.
Flavovir® can be used for children since birth.

Overdosage
Cases of overdosage are unknown. In case of the overdose of the syrup, consult a doctor.
Adverse reactions
Allergic reactions: hypersensitivity reactions can be observed in patients with increased sensation. Allergic reactions, including rash, itching, urticaria, skin hyperemia can be observed.
Gastrointestinal disorders: gastrointestinal disorders – pain in epigastric region, nausea, vomit, diarrhea can be observed (if any of this symptoms are present, take the syrup in 1,5-2 hours after meal). Esophageal reflux and recrudescence of gastroduodenitis are possible in patients with chronic gastroduodenitis.
General disorders: transient increase in body temperature up to 38 °C on the 3-10th day of treatment, headache can be observable.
If you experience any side effects, contact your doctor.

Shelf-life. 2 years.
Do not use after the expiration date printed on the package.
Storage conditions.
Store in the original package out of reach of children at the temperature less than 25 °C. Do not freeze.
After the first opening of the vial keep it closed in the original package not longer than for 30 days.
Package.
30 ml or 50 ml, or 60 ml vials made of dark glass or plastic. A dosage container shall be placed into carton package.

Category of prescription.
Without prescription.

Manufactured by:
“Scientific & Manufacturing Company “Ecopharm” LTD., 116 Shevchenka Str., Ulashanivka Village, Slavuta District, Khmelnytskyi Region., 30070, Ukraine.

Under Authorisation from:
“Scientific & Manufacturing Company “Ecopharm” LTD., 9-V, Stepana Bandery ave, Kyiv city, 04073, Ukraine.

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