MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

PATIENT INFORMATION LEAFLET

LICOPID® tablets 1 mg

Registration Number:

Trade name:

LICOPID®

Generic name:

Glucosaminylmuramyldipeptide

Chemical name:

[4-O-(2-acetylamino-2-deoxi-β-D-glucopyranosyl)-N-acetylmuramyl]-L-alanyl-D-α-glutamylamide

Dosage form:

Tablets

Description:

Round, flat-cylindrical, beveled tablets of white color.

Composition – one tablet contains:

Active substance: glucosaminylmuramyldipeptide (GMDP) – 1.0 mg.

Excipients: Lactose monohydrate – 73.88 mg, sucrose (sugar) – 5.0 mg, potato starch – 19.0 mg, methyl cellulose – 0.12 mg, calcium stearate – 1.0 mg

Pharmacotherapeutic group of the drug:

Immunomodulator

ATC code: LO3A

Pharmacological properties

Pharmacodynamics

Active substance of the Licopid tablets – glucosaminylmuramyldipeptide (GMDP) – is a synthetic analogue of the fragment of the bacteria cell wall (peptidoglycane). GMDP is an activator of the innate and adaptive immunity; enhances protection of organism against viral, bacterial and fungal infections; has adjuvant effect on the development of immunological reactions.

Biological activity of the drug occurs through binding of GMDP to NOD2 intracellular receptor protein located in cytoplasm of phagocytes (neutrophils, macrophages, dendritic cells). This drug stimulates functional (bactericidal, cytotoxic) activity of phagocytes, enhances antigen presentation and proliferation of T- and B-lymphocytes, increases synthesis of specific antibodies, and promotes normalization of the balance of Th1/Th2-lymphocytes toward Th1 prevalence. Pharmacological effect involves the enhancement of production of the key interleukins (interleukine-1, interleukine-6, interleukine-12), tumor necrosis factor-alpha, gamma interferons, colony-stimulating factors. The drug increases activity of the natural killer cells.

Licopid® has low toxicity (LD50 exceeds the therapeutic dose by more than 106 000 times). In the experiment with oral administration of the doses 100 times higher than the therapeutic dose, the drug has not exerted any toxic effect on the central nervous and cardiovascular systems, has not caused pathological changes of visceral organs. Licopid® does not exert any embryotoxic or teratogenic effect, does not cause chromosome or gene mutations. Experimental animal studies provided data on antitumor activity of Licopid® (GMDP).

Pharmacokinetics

Bioavailability of the drug after oral administration is 7-13%. Binding to serum albumins is low. Time to maximum concentration (t_{max}) is 1.5 hour after administration. Elimination half-life ($t_{1/2}$) is 4.29 hours. This drug does not have any active metabolites and is excreted unchanged by the kidneys.

Therapeutic indications

The drug is administered to adults and children (of 3 years old and upward) in complex therapy of diseases accompanied with the secondary immunodeficiency states:

Children

- Chronic recurring infections of upper and lower respiratory tracts in the exacerbation and remission phase;
- Acute and chronic pyoinflammatory skin and soft tissues diseases (pyodermatitis, furunculosis and other);
- Herpes infection.

Adults

- Chronic respiratory infections;
- Acute and chronic pyoinflammatory skin and soft tissues diseases (pyodermatitis, furunculosis and other);
- Herpes infection.

Preventive administration (adults)

- Prevention and decrease of seasonal ARD incidences, and frequency of aggravation of chronic diseases of the ENT-organs, upper and lower respiratory tracts.

Contraindications

Hypersensitivity to glucosaminylmuramyldipeptide and other components of the drug;

Pregnancy and lactation;

Autoimmune thyroiditis in the exacerbation phase;

Disorders accompanied with the febrile temperature (>38°C) at the moment of drug administration;

Rare inborn errors of metabolism: alactasia, galactosemia, lactase deficiency, lactose intolerance, sucrase/isomaltase deficiency, fructose intolerance, glucose-galactose malabsorption;

This drug is not recommended for autoimmune diseases because of the lack of clinical data.

Method of administration and posology

Licopid® is administered orally or sublingually, under fasting conditions, 30 minutes before meals.

If you miss a dose, you may take the missed dose provided that less than 12 hours has passed after the scheduled dosing time; if more than 12 hours has passed after the scheduled dosing time, take only the next dose according to the dosing scheme and skip the missed dose.

No dose correction for specific groups of patients (elderly patients, patients with liver function disorder, patients with renal function disorder) is required.

Children:

Acute and chronic pyoinflammatory skin and soft tissues diseases (pyodermatitis, furunculosis and other): 1 tablet once per day, sublingually, for 10 days.

Chronic recurring infections of upper and lower respiratory tracts (in the exacerbation and remission phase): Licopid® is administered in 3 treatment cycles with 1 tablet once per day, sublingually, for 10 days with the 20-day interval period between the treatment cycles.

Herpes infection: 1 tablet 3 times per day, orally or sublingually, for 10 days.

Adults

Chronic respiratory infections: 2 tablets once per day sublingually for 10 days.

Acute and chronic pyoinflammatory skin and soft tissues diseases (pyodermatitis, furunculosis and other): 2 tablets 2-3 times per day, sublingually, for 10 days.

Herpes infection: 2 tablets 3 times per day, orally or sublingually, for 10 days.

Preventive administration (adults)

Administration of Licopid® for prevention and decrease of seasonal ARD incidences, and frequency of aggravation of chronic diseases of the ENT-organs, upper and lower respiratory tracts: 1 tablet 3 times per day, sublingually, for 10 days.

Precautions for use

Each Licopid® tablet 1 mg contains sucrose in the amount of 0.00042 bread units that must be taken into account by patients with diabetes mellitus.

Each Licopid® tablet 1 mg contains 0.074 g of lactose that must be taken into account by patients suffering with hypolactasia (lactose intolerance at which the level of lactose – enzyme required for lactose digestion – is decreased in the organism).

Overdose

No overdose of the drug has been reported.

Based on pharmacological properties of the drug, its overdose may cause the increase of temperature up to subfebrile values (up to 37.9°C). If necessary, symptomatic therapy is performed (antipyretics) and the sorbents are prescribed. No specific antidote is known.

Side effects

Frequent (1-10%) – at the beginning of treatment the short-term increase of temperature up to subfebrile values (up to 37.9°C) can occur but it does not constitute an indication to discontinue the drug.

Rare (0.01-0.1%) – short-term increase of temperature up to febrile values (> 38.0°C). When the body temperature is higher than 38.0°C antipyretics may be used as they do not reduce pharmacological effects of Licopid® tablets.

Very rare (less than 0.01%) – diarrhea.

In case of aggravation of any of the side effects listed in this Patient Information Leaflet or if you noted any other side effects not listed herein, please, report to the doctor.

Interaction with other medicines

Licopid® increases the efficiency of antibacterial drugs and has synergistic interaction with antiviral and antifungal drugs. Antacids and sorbents significantly reduce the availability of the drug. Glucocorticosteroids reduce the biological effect of Licopid®.

Use during pregnancy and lactation

Administration of Licopid® 1 mg **is contraindicated** for women during pregnancy and lactation.

Special precautions

At the beginning of the administration of Licopid® 1 mg, symptoms of chronic and latent diseases can aggravate due to the main pharmacological effects of the drug.

Effects on ability to drive and use machines

Licopid® does not influence the ability to drive and use complex machinery.

Shelf life.

5 years.

Do not use after expiration date.

Presentation.

1 mg tablets.

10 tablets in a blister made of polyvinylchloride film and printed lacquered aluminum foil.

1 or 3 blisters packed in a carton pack together with Patient Information Leaflet.

Storage conditions.

Store in a dry place protected from light at the temperature not exceeding 25ºC.

Keep out of reach of children.

Pharmacy purchasing terms.

Available without prescription.

Marketing Authorization holder

"Peptek" JSC, Russia

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If necessary, use the above address, e-mail and phone of "Peptek" JSC to get more information on the drug product, report the adverse drug reactions developed during drug administration (side effects) or send quality complaint.

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