MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

PATIENT INFORMATION LEAFLET

LICOPID® tablets 10 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 and scored tablets of white color.

Composition – one tablet contains:

Active substances: glucosaminylmuramyldipeptide (GMDP) – 10.0 mg.

Excipients: lactose monohydrate – 184.7 mg, sucrose (sugar) – 12.5 mg, potato starch – 40 mg, methyl cellulose – 0.3 mg, calcium stearate – 2.5 mg

Pharmacotherapeutic group of the drug product:

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 49 000 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 for complex therapy of diseases accompanied with the secondary immunodeficiency states:

- Acute and chronic pyoinflammatory skin and soft tissue diseases, including pyo-septical postsurgical complications;
- Sexually-transmitted infections (papillomavirus infection, chronic trichomoniasis);
- Herpes infection (including ophthalmic herpes);
- Psoriasis (including psoriatic arthritis);
- Pulmonary tuberculosis.

Contraindications

Hypersensitivity to glucosaminylmuramyldipeptide and other components of the drug;

Pregnancy and lactation;

Children under the age of 18;

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 under fasting conditions, 30 minutes before meals.

For the elderly patients, it is recommended to start therapy with the half doses (1/2 of the therapeutic dose) and to increase the dose of the drug up to the required therapeutic dose if no side effects occur.

*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***.**

Pyoinflammatory skin and soft tissue diseases, acute and chronic, severe course, including pyo-septical postsurgical complications: 10 mg once per day for 10 days;

Herpes infection (recurrent attacks, severe forms): 10 mg once per day for 6 days.

Ophthalmic herpes: 10 mg twice per day for 3 days. Repeat treatment after a break period of 3 days.

Sexually-transmitted infections (papillomavirus infection, chronic trichomoniasis):

- papillomavirus infection: 10 mg once per day for 10 days;
- chronic trichomoniasis: 10 mg once per day for 10 days;

Psoriasis: 10-20 mg once per day for 10 days followed by 5 doses of 10-20 mg once per day taken every other day.

For *severe* psoriasis and gross lesions (including psoriatic arthritis): 10 mg twice per day for 20 days.

Pulmonary tuberculosis: 10 mg once per day for 10 days.

Precautions for use

Each Licopid® tablet 10 mg contains sucrose in the amount of 0.001 bread units that must be taken into account by patients with diabetes mellitus.

Each Licopid® tablet 10 mg contains 0.184 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).

Be careful

Licopid® 10 mg shall be used for the elderly patients with special care and strictly under medical supervision.

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%) – arthralgias (joint pain), myalgias (muscle pain); 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. At most, these side effects occur when Licopid® tablets are taken at high doses (20 mg).

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® 10 mg **is contraindicated** for women during pregnancy and lactation.

Special precautions

At the beginning of administration of Licopid® 10 mg, the symptoms of chronic and latent diseases can aggravate due to the main pharmacological effects of the drug.

Licopid® 10 mg shall be administered to elderly people with special care, strictly under medical supervision. For the elderly patients, it is recommended to start therapy with the half doses (1/2 of the therapeutic dose), and to increase the dose of the drug up to the required therapeutic dose if no side effects occur.

Decision on prescription of Licopid® tablets 10 mg to patients with combined diagnoses of “psoriasis” and “gout” must be made by the **doctor** after benefit/risk assessment because of the potential risk of aggravation of the gouty arthritis and joint swelling. If the **doctor** decides to prescribe Licopid® tablets 10 mg in the circumstances when a patient has combination of diagnoses of “psoriasis” and “gout”, treatment must be started with the low doses, increasing the dose up to the therapeutic dose if no side effects occur.

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.

Pharmacy purchasing terms.

Available on prescription.

Presentation.

10 mg tablets.

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

Marketing Authorization holder

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www.peptek.ru www.licopid.ru

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If necessary, use the above address, e-mail and phone 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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