

**INSTRUCTION
for medical use
of medicinal product
LEKSOL®**

Composition:

active ingredients: benzocaine, bismuth subgallate, zinc oxide, menthol;

1 suppository contains benzocaine (0.1 g) 100 mg, bismuth subgallate (0.04 g) 40 mg, zinc oxide (0.02 g) 20 mg, menthol (0.004 g) 4 mg;

excipients: polyethylene oxide 1500, polyethylene oxide 400.

Dosage form. Suppositories.

Main physicochemical properties: green-yellow, bullet-shaped suppositories.

Pharmacotherapeutic group. Agents for treatment of hemorrhoids and anal fissures for topical use. Local anesthetics. ATC code C05A D.

Pharmacological properties.

Pharmacodynamics.

Leksol® is a complex medicinal product, therapeutic effect of which is due to pharmacological properties of active ingredients in its composition. Leksol® exerts local anesthetic, anti-inflammatory, and astringent effect.

Pharmacokinetics.

Has not been studied.

Clinical particulars.

Indications.

Symptomatic therapy of hemorrhoids and anal fissures.

Contraindications.

Hypersensitivity to the drug product ingredients. Hypersensitivity to other amide anesthetic agents.

Interaction with other medicinal products and other forms of interaction.

Have not been studied.

Administration details.

Monitoring of blood parameters is necessary in the conditions of long-term use.

Pregnancy and lactation.

The drug product may be prescribed to pregnant or breastfeeding women by a doctor with consideration of risk/benefit ratio.

Effects on ability to drive and use machines.

It is recommended to abstain from driving and performing works requiring increased attention and precise coordination during the period of treatment with this product.

Posology and method of administration.

The following should be done before using the suppository:

- tear off one suppository in primary package along the blister package perforation line;
- further, pull the film edges tearing it apart, and release the suppository from primary package.

The drug product is administered by rectal route. 1 suppository 1-2 times daily after an intestinal purgative enema or independent defecation.

The treatment duration is established by a doctor with consideration of the disease course and severity, as well as therapeutic effect achieved.

Children. No data regarding the use of this drug product in children are available.

Overdose.

Overdose is unlikely in case the drug product is used in therapeutic doses. Enhancement of adverse reaction manifestations is possible. Therapy is symptomatic.

Adverse reactions.

Allergic reactions, skin rash, and itching develop occasionally. The drug product can exert laxative effect and cause itching in anus. Blood disorders (methemoglobinemia) can develop in the conditions of long-term use.

Shelf life. 3 years.

Storage conditions. Store at temperature not exceeding 25 °C. Keep away from children.

Package. 5 suppositories in a blister, 1 or 2 blisters in a pack.

Dispensing category. Over-the-counter drug.

Manufacturer. Joint Stock Company «Lekhim-Kharkiv».

Manufacturer's location and place of business.

Ukraine, 61115, Kharkiv region, Kharkiv, Severyna Pototskoho street, building 36.

Date of the last revision.