

# Phosphogliv® Forte

**INTERNATIONAL NON-PROPRIETARY NAME (INN):** phospholipids + glycyrrhizic acid

## **DOSAGE FORM AND STRUCTURE:**

*Active ingredients:* Phospholipids (Lipoid PPL-400) 400.0 mg; phosphatidylcholine (the main component 73-79%) 300.0 mg; sodium glycyrrhizinate (trisodium salt of glycyrrhizic acid) 65.0 mg.

*Excipients:* butylhydroxytoluene 0.1 mg; ethyl alcohol of "lux" or "extra" grade (ethanol) 12 mg; sunflower or corn oil 22.9 mg.

*The composition of the capsule shell:* titanium dioxide, red iron oxide, black iron oxide, yellow iron oxide, gelatin.

**DESCRIPTION:** hard gelatin capsules No. 0. The capsule body and cap are brown. The content of the capsule is an oily pasty mass with a faint specific smell, its color varies from light yellow to orange-brown.

## **PHARMACOLOGICAL CLASSIFICATION:**

Nosological classification (ICD-10):

- B19 Unspecified viral hepatitis
- K70 Alcoholic liver disease
- K71 Toxic liver disease
- K74 Fibrosis and cirrhosis of liver
- K76.0 Fatty change of liver, not elsewhere classified
- L20.8 Other atopic dermatitis
- L30.9 Dermatitis, unspecified
- L40 Psoriasis
- X49 Accidental poisoning by and exposure to other and unspecified chemicals and noxious substances

**PHARMACOLOGICAL GROUP:** hepatoprotective agent

**ATC CODE:** A05BA Liver therapy

**PHARMACOLOGICAL ACTION:** anti-inflammatory, hepatoprotective, metabolic, membrane-stabilizing.

## **PHARMACODYNAMICS:**

Combination medicine. It has a membrane stabilizing, hepatoprotective and antiviral effect.

*Phosphatidylcholine* (the main component of phospholipids) is the main structural element of the cell and intracellular membranes; it is able to restore their structure and function upon damage, providing a cytoprotective effect. It normalizes protein and lipid metabolism, prevents the loss of enzymes and other active substances by hepatocytes. It restores the detoxification function of the liver, inhibits the formation of connective tissue, reducing the risk of liver fibrosis and cirrhosis.

**Glycyrate** (glycyrrhizic acid and salts) has an anti-inflammatory effect; it inhibits the reproduction of viruses in the liver and other organs by stimulating the production of interferons, increasing phagocytosis and the activity of natural killer-cells. It has a hepatoprotective effect due to antioxidant and membrane stabilizing activity. It potentiates the action of endogenous glucocorticosteroids, providing an anti-inflammatory and anti-allergic effect in non-infectious liver lesions. In case of skin lesions, the membrane-stabilizing and anti-inflammatory action of the medication components is known to limit the spread of the process and it contributes to the regression of the disease.

#### **PHARMACOKINETICS:**

**Phosphatidylcholine.** More than 90% of the phospholipids taken orally are absorbed in the small intestine. Most of them are split by phospholipase A to 1-acetyl-lysophosphatidylcholine, 50% of which undergoes reverse acetylation to polyunsaturated phosphatidylcholine during absorption in the intestinal mucosa. Polyunsaturated phosphatidylcholine enters the bloodstream with the lymph flow, from where it mainly enters the liver in the form associated with high density lipoproteins. Pharmacokinetics in humans has been studied using dilenoleylphosphatidylcholine with a radioactive label <sup>3</sup>H (choline part) and <sup>14</sup>C (residue of linoleic acid). The maximum concentration of <sup>3</sup>H is reached after 6-24 hours, amounting to 19.9% of the prescribed dose; <sup>14</sup>C - after 4-12 hours, amounting to 27.9%. The half-life of the choline component is 66 hours, the residue of linoleic acid - 32 hours. There is 2% of <sup>3</sup>H and 4.5% of <sup>14</sup>C in feces, in urine - 6% of <sup>3</sup>H and a minimum amount of <sup>14</sup>C. More than 90% of both isotopes is absorbed in the intestine.

**Glycyrrhizin acid.** Under the influence of the  $\beta$ -glucuronidase enzyme produced by bacteria of the normal microflora, an active metabolite -  $\beta$ -glycyrrhetic acid - is formed from glycyrrhizic acid in the intestine after an oral administration, it is then absorbed into the systemic blood flow. In blood,  $\beta$ -glycyrrhetic acid binds to albumin and is almost completely transported to the liver. The release of  $\beta$ -glycyrrhetic acid occurs predominantly with bile, in residual quantities - with urine. According to experimental data, phospholipids improve the lipophilic properties of glycyrrhizic acid, increasing its intensity and absorption rate by more than 2 times.

**INTENDED USES:** Fatty liver disease (fatty hepatosis); alcoholic, toxic, including drug-induced, liver injury; as part of the complex therapy of viral hepatitis, cirrhosis, psoriasis.

#### **CONTRAINDICATIONS:**

Antiphospholipid syndrome; use in patients with intolerance to corn or corn products (the component being a part of excipients may contain corn oil); hypersensitivity to the drug components; pregnancy, the period of breastfeeding; children under 12 years old.  
With caution: portal hypertension, arterial hypertension.

#### **DOSAGE AND ADMINISTRATION:**

The drug is taken orally during meals, with a small amount of liquid. Adults - 1-2 capsules 3 times a day, children over 12 years old - 1 capsule 3 times a day. The duration of the course of treatment is determined by the doctor.

#### **PRECAUTION:**

If there is retention of sodium and fluid or hypokalemia, it is necessary to reduce the dose of the drug and / or prescribe Spironolactone 50-100 mg, depending on the symptoms severity.

#### **SIDE EFFECTS:**

Allergic reactions: skin rash, difficulty in nasal breathing, conjunctivitis, cough.  
Cardiovascular system: transient increase in blood pressure, peripheral edema.

Digestive system: dyspeptic symptoms (burping, nausea, bloating), a feeling of discomfort in the stomach.

If these symptoms occur, stop taking the drug and consult the doctor.

**OVERDOSE:**

Symptoms of an overdose: sodium and fluid retention in the body, manifested in peripheral edema and increased blood pressure; hyponatremia.

Treatment: depending on the severity of the symptoms of an overdose, it is necessary to reduce the dose of the drug and / or prescribe Spironolactone (50-100 mg per day).

**INTERACTION WITH OTHER DRUGS:**

Glycyrrhizic acid is a synergist of corticosteroid hormones, it enhances and prolongs their effect.

**PREGNANCY AND LACTATION:**

The drug is contraindicated during pregnancy and breastfeeding (data on efficacy and safety are insufficient).

**INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE**

**MECHANISMS:**

The use of the drug does not affect the ability to drive vehicles and engage in other potentially dangerous activities that require the increased concentration of attention and speed of psychomotor reactions.

**STORAGE CONDITIONS:**

Store in a dry place, at a temperature not exceeding 25 ° C (77.0 ° F). Keep out of the reach of children.

**SHELF LIFE:**

3 years. Do not use beyond the expiration date.

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