

# Derinat®

**INTERNATIONAL NON-PROPRIETARY NAME (INN):** Sodium Deoxyribonucleate.

## **DOSAGE FORM AND STRUCTURE:**

### **Composition (spray):**

*Active ingredient:* sodium deoxyribonucleate - 0.025 g;

*Excipients:* sodium chloride - 0.010 g; water for injection - up to 10 ml.

### **Composition (ampules):**

*Active ingredient:* sodium deoxyribonucleate - 75 mg;

*Excipients:* sodium chloride - 45 mg, water for injection - up to 5 ml.

## **DESCRIPTION:**

**Derinat® spray:** clear, colorless liquid without additives. 10 ml in bottles of colorless or brown glass, corked with a spray with a protective cap.

**Derinat® ampules:** clear, colorless liquid. 5 ml in vials of colorless or brown glass hermetically sealed with a rubber stopper and rolled in an aluminium cap with a tear-off plastic overlay.

## **ATC CODE:**

**Derinat® spray:** L03 (Immunostimulants), V03AX (Other therapeutic products).

**Derinat® ampules:** L03 (Immunostimulants), V03AX (Other therapeutic products), B03XA (Other antianemic preparations).

## **PHARMACOLOGICAL ACTION:**

**Derinat® spray:** immunomodulating agent, tissue repair stimulant.

**Derinat® ampules:** immunomodulating agent, hematopoiesis stimulant, regenerative agent.

## **PHARMACODYNAMICS:**

### **Derinat® spray:**

The drug activates the cellular and humoral immunity. It optimizes specific reactions against fungal, viral and bacterial infections. The drug stimulates reparative and regenerative processes, normalizes the state of tissues and organs in case of dystrophy of the vascular origin. Derinat® facilitates the healing of trophic ulcers of various etiologies and promotes the rapid healing of deep burns, significantly accelerating the dynamics of epithelization. Derinat® stipulates scarless recovery in restoration of ulcerative formations on the mucous membrane. The drug does not have teratogenic and carcinogenic effects.

### **Derinat® ampules:**

The drug activates processes of the cellular and humoral immunity. The immunomodulatory effect is due to the stimulation of B-lymphocytes, and the activation of T-helpers. Derinat® activates the nonspecific resistance of the body, optimizing the inflammatory response, and the immune response to bacterial, viral and fungal antigens. It stimulates reparative and regenerative processes, increases the body's resistance to infections and regulates haematopoiesis (helps normalize the number of leucocytes, lymphocytes, granulocytes, phagocytes and platelets). Due to its pronounced lymphotropy, Derinat® stimulates the drainage and

detoxification function of the lymphatic system. Derinat® significantly reduces the cell sensitivity to the damaging effects of chemotherapeutic drugs and radiation therapy. The drug does not have embryotoxic, teratogenic and carcinogenic effects.

### **PHARMACOKINETICS:**

#### **Derinat® spray:**

When applied locally, Derinat® is rapidly absorbed and distributed in organs and tissues with the participation of the endolymphatic transport route. In the phase of the intensive drug intake into the blood, the redistribution occurs between the plasma and blood cells, in parallel with metabolism and excretion. Derinat® is metabolized in the body. Most of the drug is excreted from the body (in the form of metabolites) with urine according to biexponential dependence and partially with feces.

#### **Derinat® ampules:**

*Absorption and distribution.* The drug is rapidly absorbed and distributed in organs and tissues with the participation of the endolymphatic transport route. It has high tropism to the organs of the hematopoietic system, and takes an active part in the cellular metabolism, integrating into cellular structures. In the phase of the intensive drug intake into the blood, the redistribution occurs between the plasma and blood cells, in parallel with metabolism and excretion. After a single injection, all pharmacokinetic curves describing the change in the concentration of the drug in the studied organs and tissues are characterized by a quick phase of the increase and a decrease in concentration in the time interval of 5 to 24 hours. The half-life ( $T_{1/2}$ ) for intramuscular administration is 72.3 hours. Derinat® is quickly distributed throughout the body. During the daily course treatment it accumulates in organs and tissues: to a greater degree - in the bone marrow, lymph nodes, spleen and thymus; to a lesser degree - in the liver, brain, stomach, small and large intestines. The maximum concentration in the bone marrow is identified 5 hours after an intake. The drug penetrates through the blood-brain barrier. The maximum concentration of the drug in the brain is reached after 30 minutes.

*Metabolism and excretion.* Derinat® is metabolized in the body. Most of the drug is excreted from the body (in the form of metabolites) with urine according to biexponential dependence and partially with feces.

### **INTENDED USES:**

#### **Derinat® spray:**

##### **Monotherapy:**

- Acute respiratory infections;
- Prevention and treatment of acute respiratory viral infections (ARVI);
- Inflammatory diseases of the mucous membranes of the oral cavity;

##### **Complex therapy:**

- Chronic inflammatory diseases, fungal, bacterial and other infections of the mucous membranes in gynecology;
- Acute and chronic diseases of the upper respiratory tract (rhinitis, sinusitis, maxillitis, frontal sinusitis);
- Obliterating diseases of the lower extremities;
- Trophic ulcers, long-term non-healing and infected wounds (including in diabetes mellitus);
- Gangrene;
- Burns, frostbite;
- Hemorrhoids;
- Post-radiation necrosis of skin and mucous membranes.

#### **Derinat® ampules:**

- Radiation injuries;
- Inhibition of haematopoiesis;
- Cancerous myelodysplastic syndrome and resistance to cytostatics under the cytostatic and / or radiation therapy (haematopoiesis stabilization, decrease of chemical cardio- and myelotoxicity);
- Stomatitis, induced by cytostatic therapy;
- Stomach and peptic ulcer disease, erosive gastroduodenitis;
- Ischemic heart disease;
- Obliterating diseases of vessels of the lower extremities, chronic ischemia of the lower extremities of II - III stage;
- Trophic ulcers, chronic non healing wounds;
- Odontogenic sepsis, suppurative-septic complications;
- Rheumatoid arthritis;
- Burn disease;
- Preoperative and postoperative periods (in surgery);
- Endometritis, salpingo oophoritis, endometriosis, myoma;
- Chlamidiosis, ureaplasmosis, mycoplasmosis;
- Prostatitis, benign prostatic hyperplasia;
- Chronic obstructive pulmonary disease;
- Pulmonary tuberculosis, inflammatory diseases of the respiratory tract.

#### **CONTRAINDICATIONS:**

Individual intolerance to the drug components.

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

##### **Derinat® spray:**

The drug is prescribed for children from the first day of life and for adults.

- For the prevention of acute respiratory viral infections, 1 spray is inserted into each nasal passage 2-4 times a day for 1-2 weeks.
- In acute respiratory infections, acute respiratory viral infections, 1 to 2 sprays are inserted into each nasal passage every 1-1.5 hours during the first day; then - 1 spray into each nasal passage 3-4 times a day. The course duration is 1 month.
- In inflammatory diseases of the nasal cavity and paranasal sinuses, 1-2 sprays of the drug are inserted into each nasal passage 4-6 times a day. The duration of the course is 7-15 days.
- In diseases of the oral mucosa, the rinsing is carried out 4-6 times a day (1 bottle - 1-2 rinses), or the drug is evenly sprayed onto the damaged sections of the mucosa, 2-3 sprays 4-6 times a day. The length of the treatment is 10 days.
- In chronic inflammatory diseases, fungal, bacterial and other infections in gynecology: an intravaginal administration with irrigation of the cervix uteri or an intravaginal administration of tampons moistened with the drug in the amount of 5 ml per procedure, 1-2 times a day for 10-14 days.
- In hemorrhoids, the drug is prescribed in the form of microclysters into the rectum in the amount of 15-40 ml. The length of the therapy is 10 days.\
- In obliterating diseases of the lower extremities, the drug is instilled into the nose, 1-2 drops into each nasal passage 6 times a day; the course duration is up to 6 months.
- In post radiation necrosis of skin and mucous membranes, in case of long-term non-healing wounds, burns, frostbite, trophic ulcers of various etiologies and gangrene, applications are put on the affected areas 3-4 times a day, or the affected area is treated with Derinat® spray 4-5 times a day, in the amount of 10-40 ml (the treatment course is 1-3 months).

##### **Derinat® ampules:**

Adults: the content of the ampule is injected intramuscularly for 1-2 minutes, 5 ml of the solution, with an interval of 24-72 hours.

- In coronary heart disease: 10 injections with an interval of 48-72 hours.
- In peptic ulcer of the stomach and duodenum: 5 injections with an interval of 48 hours.
- In cancer: 3-10 injections with an interval of 24-72 hours.
- In gynecology (endometritis, chlamydia, ureaplasmosis, mycoplasmosis, salpingo oophoritis, myoma, endometriosis): 10 injections with an interval of 24-48 hours.
- In andrology (prostatitis, benign prostatic hyperplasia): 10 injections with an interval of 24-48 hours.
- In pulmonary tuberculosis: 10-15 injections with an interval of 24-48 hours.
- In acute inflammatory diseases: 3-5 injections with an interval of 24-72 hours.
- In chronic inflammatory diseases: 5 injections with an interval of 24 hours, then 5 injections with an interval of 72 hours.

Children: the drug is prescribed intramuscularly in the same mode as for adults. For children under 2 years old, the drug is prescribed in a single dose of 7.5 mg (0.5 ml). For children from 2 to 10 years old, the drug is prescribed in a dose of 0.5 ml of the drug per one year of life. For children from 10 years old, a single dose is 5 ml of a solution; the course is up to 5 injections.

### **SIDE EFFECTS:**

Derinat® spray: in gangrenous processes spontaneous rejection of necrotic masses in the centers of rejection with the following restoration of the skin is noted under the influence of the drug. In open wounds and burns, an analgesic effect is observed.

Derinat® ampules: in patients with diabetes mellitus, a hypoglycemic effect may be noted, which should be taken into account during the blood glucose monitoring.

*If you notice any other side effects not listed in the description, notify your doctor.*

### **OVERDOSE:**

No cases of the drug overdose have been reported.

### **INTERACTION WITH OTHER DRUGS:**

#### **Derinat® spray:**

When applied locally, the drug is not compatible with fat-based ointments and hydrogen peroxide.

#### **Derinat® ampules:**

The use of Derinat® in the complex therapy can increase the effectiveness and reduce the duration of the treatment, significantly decreasing the doses of antibiotics and antiviral agents and increasing the period of remission.

Derinat® increases the effectiveness of anthracycline antitumor antibiotics and cytostatics.

The drug potentiates the therapeutic effect of the basic therapy in gastric and duodenal ulcer. It reduces the iatrogenicity of basic drugs in the treatment of rheumatoid arthritis with a 50% and 70% improvement in a number of complex indicators of the disease activity.

In surgical sepsis, the administration of Derinat® as part of the complex therapy stipulates a decrease in the level of intoxication, the activation of immunity and normalization of hematopoiesis; it improves the functioning of the organs responsible for the detoxification of the internal environment of the body (lymph nodes, spleen, etc.).

### **PREGNANCY AND LACTATION:**

Consultation with the doctor is required. If the drug is prescribed during pregnancy it is necessary to assess the expected benefits for the mother and the potential risk to the fetus. The drug administration during breastfeeding should be carried out strictly according to the doctor's prescription.

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

### **MECHANISMS:**

The use of Derinat® does not affect the ability to perform potentially dangerous activities that require the increased concentration of attention and the speed of psychomotor reactions (including driving and working with moving mechanisms).

### **STORAGE CONDITIONS:**

Store in a dark place at a temperature from + 4°C (39.2°F) to + 20°C (68°F). Keep out of the reach of children.

### **SHELF LIFE:**

5 years. Do not use after the expiry date indicated on the package. The contents of the opened bottle of **Derinat® spray** should be used within two weeks. Do not use the unclaimed contents of the opened **Derinat® ampules**.

**MANUFACTURER:** "PharmPack" Company. <http://derinat.com/en/>