Longidaza® 3000 IU (powder for preparing a solution for injection)

Name in Cyrillic : Лонгидаза

this instruction is translated from original Russian instructions by Extrapharmacy.<u>https://extrapharmacy.ru</u>

1 vial (ampoule) with powder for preparing a solution for parenteral use of Longidaza® contains: Hyaluronidase conjugate with a copolymer (N-oxide 1,4-ethylene piperazine and (N-carboxymethyl) -1,4-ethylene piperazinium bromide) - 3000 IU

Pharmachologic action:

Longidaza® has pharmacological properties inherent in preparations with hyaluronidase activity. In particular Longidaza® has a pronounced anti-edema, antioxidant, anti-inflammatory, chelating and immunomodulatory effects.

Specific substrates of hyaluronidase are glycosaminoglycans (in particular, chondroitin, hyaluronic acid, chondroitin-6-sulphate and chondroitin-4-sulphate) - substances of the connective tissue. As a result of glycolysis - a decrease in the viscosity of glycosaminoglycans is noted, the ability to bind metal ions and water, thus increases the permeability and trophicity of tissues, decreases the severity of swelling and hematomas, increases the elasticity of cicatricial sites, and improves mobility of joints. The most pronounced effect of Longidaza® gives in the initial stages of the pathological process.

The effectiveness of Longidaza[®] significantly exceeds that of native hyaluronidase, since conjugation contributes to an increase in the resistance of the enzyme to the effects of temperatures and inhibiting substances.

The antioxidant effect of Longidaza® is due to the ability of the active substance to bind the released iron ions, which activate free-radical reactions, stimulants of collagen synthesis and hyaluronidase inhibitors. The polytropic properties of the drug are realized in the anti-fibrotic effect, which is proved by biochemical, electron microscopic and histological studies on a pneumofibrosis model.

Longidaza® regulates the synthesis of inflammatory mediators, weakens the course of the acute phase of the inflammatory process, stimulates humoral immunity and increases the body's resistance to infections.

The drug does not worsen the postoperative period, does not cause the progression of the infectious process, does not adversely affect the recovery of bone tissue. Such properties allow the use of Longidaza® as a means of preventing severe scarring and adhesions after surgery. With simultaneous parenteral administration Longidaza® enhances the absorption of other drugs and accelerates the action of local anesthetics.

Longidaza® is a low toxic drug that does not affect the normal function of the immune and re-

productive systems. Longidaza® does not have mutagenic, carcinogenic and teratogenic effects. When Longidaza® is administered parenterally - the active component is rapidly absorbed into the systemic circulation, reaching peak values in the plasma within 20-25 minutes. The half-life of the active ingredient with intramuscular injection reaches 36 hours, with subcutaneous administration - 45 hours. The bioavailability of the drug when administered parenterally reaches 90%.

The active component of Longidaza® penetrates through the hematoplacental, hematoence-phalic and ophthalmologic barriers.

Hyaluronidase is hydrolyzed in the body, the carrier disintegrates into oligomers and is excreted by the kidneys in two phases. Fully Longidaza[®] is excreted from the body within 4-5 days after parenteral administration.

Indications for use

Longidaza® injections are used in the treatment of patients suffering from diseases that are accompanied by connective tissue hyperplasia.

In particular Longidaza® used:

<u>In gynecological practice</u> with adhesive processes in the small pelvis, which are accompanied by inflammatory diseases of the internal genital organs (including intrauterine synechia, tubo-peritoneal infertility and chronic endometritis).

In urological practice for chronic prostatitis and interstitial cystitis.

<u>In surgical practice</u> during adhesions after surgery on the abdominal cavity, hypertrophic scars after burns, injuries, surgeries, pyoderma, as well as nonhealing wounds.

<u>In dermatovenerological and cosmetological practice</u> with limited scleroderma, emerging, keloid and hypertrophic scars after pyoderma, operations, injuries and burns.

<u>In pulmonary practice and phthisiology</u> with pneumosclerosis, cavernous fibrosis or infiltrative tuberculosis, tuberculoma, fibrosing alveolitis.

In orthopedics for joint contracture ankylosing spondyloarthritis, arthrosis and hematomas.

Also Longidaza® can be used to increase the bioavailability of antimicrobials and local anesthetics in urological, gynecological, pulmonary and dermatovenerological practice.

According to the decision of the doctor Longidaza® can be prescribed as a prevention of the formation of scars and strictures after surgical interventions.

Mode of application

Longidaza powder is intended for preparation of a solution for parenteral use. The prepared solution is intended for intramuscular, subcutaneous and intracutaneous injection.

Intravenous administration of the Longidaza solution is forbidden.

Subcutaneously the solution is injected near the site of injury or under the scar tissue.

To prepare the solution add 1.0-2.0 ml of a 0.25-0.5% solution of procaine (with procaine intolerance, it should be replaced with 0.9% sodium chloride solution or water for injection). When preparing a solution to increase the bioavailability of drugs, the contents of the vial are dissolved in 2 ml of isotonic sodium chloride solution. The solvent must be introduced into the vial slowly, after a few minutes the solution is gently mixed without being shaken (quick introduction of the solvent or shaking the vial can lead to foaming of the protein). The ready solution is used immediately; it is forbidden to store the ready solution.

The duration of therapy and the dose of Longidaza should be determined by the doctor.

Preventive doses:

As a preventive measure for the formation of adhesions and scars after surgery it is usually prescribed to administer 3000 IU of Longidaza 1 time in 72 hours. The total course dose of the drug is 5 injections. Depending on the risk of developing adhesions the course dose may be increased up to 10 injections (in this case, injections should be given with an interval of 5 days).

Therapeutic doses:

In gynecological practice, during adhesions: 3000 IU of the drug Longidaza intramuscularly every 3-5 days is usually prescribed. The total course dose is 10-15 injections.

In gynecological practice, for tuboperitoneal infertility: usually 3000 IU of the drug Longidaza intramuscularly every 3 days is usually prescribed, after 5 injections the interval between injections is increased to 5 days. The total course dose is 15 injections.

In urological practice, for chronic prostatitis and interstitial cystitis: 3000 IU of the drug Longidaza intramuscularly is usually prescribed in doses of 1 time per 5 days. The total course dose is 10-15 injections.

In surgical practice with adhesive disease after surgery: 3000 IU of the drug Longidaza intramuscularly 1 time in 3-5 days is usually prescribed. The total course dose is 10-15 injections.

In surgical practice, with long-term non-healing wounds: 3000 IU of Longidaza® intramuscularly 1 time in 5 days is usually prescribed. The total course dose is 5-10 injections.

In dermatovenerological and cosmetological practice with limited scleroderma: usually 3000-4500 IU of Longidaza® intramuscularly is prescribed intramuscularly 1 every 3-5 days. The total course dose is up to 20 injections.

In dermatovenerological and cosmetological practice, with keloid, emerging and hypertrophic scars after burns, pyoderma and wounds: 3000–4500 IU of Longidaza subcutaneously or intratubularly is prescribed 1 time in 3 days. The total course dose is up to 15 injections. The course can be extended to 25 injections with a mandatory increase in the interval between injections

up to 5 days. According to the decision of the doctor, you can alternate the intratubular and intramuscular administration of Longidaza®.

In pulmonary practice and phthisiology it is usual to prescribe 3000 IU of Longidaza® intramuscularly 1 time in 5 days. The total course dose for pneumosclerosis is 10 injections, with fibrosing alveolitis - 15 injections with further supportive therapy (1 administration in 10 days with a course of up to 25 injections), with tuberculosis - 25 injections (with a possible extension of therapy to 6-12 months with the introduction of 3000 IU Longidaza® 1 every 10 days).

In orthopedic practice for contracture of the joints, hematomas, arthrosis, and ankylosing spondyloarthrosis: 3000 IU of the Longidaza® preparation subcutaneously is usually prescribed subcutaneously near the site of injury 1 time in 3 days. The total course dose is 5-15 injections. If necessary, the course of therapy is extended, increasing the interval between injections up to 5 days.

To increase the bioavailability of drugs: 1500 IU of Longidaza® is administered 10-15 minutes before the main drug is introduced into the same place as the main drug.

Prohibited the introduction of Longidaza® in areas with acute infectious inflammation. When skipping a dose - it should be administered as early as possible, but do not double the dose of Longidaza.

In severe chronic productive processes in the connective tissue, after a standard course of therapy - long-term maintenance therapy is prescribed (3000 IU of Longidaza® 1 every 10-14 days). Patients with renal insufficiency should not be prescribed more than 3000 IU of Longidaza® per week.

Side effects

Local or systemic allergic reactions are possible. It is also possible for patients to develop local reactions in the form of pain at the injection site, hyperemia, itching and swelling at the injection site. Local reactions as a rule do not require the abolition of the drug and independently pass within 24-72 hours.

Contraindications

Longidaza® is not used to treat patients with known hypersensitivity to the components of the powder to prepare a solution for injection.

Longidaza® is not used for the treatment of patients with malignant neoplasms, as well as severe renal impairment.

Longidaza injections should not be prescribed to patients with pulmonary hemorrhage, hemoptysis, acute forms of infectious diseases, as well as recent vitreous hemorrhage.

In pediatric practice Longidaza injections are not used.

Precautions should be prescribed Longidaza® for patients with renal insufficiency, as well as patients who have recently had bleeding.

Pregnancy

Longidaza[®] is not used in the treatment of pregnant and lactating women. If you can not avoid use Longidaza[®] during lactation - you should interrupt breastfeeding.

Drug interaction

Longididase potentiates the action of antimicrobial agents, local anesthetics and diuretic drugs with combined use.

With the simultaneous use of high doses of salicylates, cortisone, estrogen, adrenocorticotropic hormone and antihistamines reduce the effectiveness of Longidaza®.

Not recommended simultaneous use of Longidaza® with furosemide, phenytoin and benzodiazepines.

Overdose

With the use of excessive doses of Longidaza® in patients may develop chills, dizziness, increase in body temperature, as well as lower blood pressure.

There is no specific antidote. With the development of signs of overdose should stop the administration of Longidaza® and if necessary - to conduct symptomatic therapy.

Storage conditions

Longidaza® should be stored in rooms with a temperature range from 8 to 15 degrees Celsius for a period of not more than 2 years.

Ready solution for parenteral use of Longidaza® is not a subject for storage.

Manufactured by Petrovax Pharm (Russia)

Reliable vendor with fast shipping Worldwide: Extrapharmacy Online Store https://extrapharmacy.ru