

INSTRUCTION

for the clinical study of antivirus, antitumor, antimicrobial and immune correcting izatizon preparation

Izatizon is an original complex preparation (patent of Ukraine N° 1786, 29.10.93), which is composed of preparations used as independent remedies in medical practice of former USSR, Ukraine, Russian Federation and other countries: methysason (marboran), dimethyl sulfoxide, polyethylene glycol (tween) of molecular weight 400. The preparation is approved in veterinary of Ukraine and Russia for prevention and treatment of virus and microbe-virus diseases of poultry, domestic and agricultural animals, furry animals and bees.

Physical-chemical properties – oily liquid of dark-yellow color, has a bitter taste and a specific smell. Hardens at $-10 - -15^{\circ}$ C. Possesses no flammable or explosive features.

Pharmacological properties. Izatizon belongs to the group of substances of little toxicity. Possesses antiseptic and antiphlogogenic action. Does not oppress hematois, has no cumulative properties. Decreases the manifestations of anaphylactic shock when used during the inductive phase of immunogenesis, is able to regulate the indices of specific and non-specific resistance at disorders of the organism immune status by causing the activity increase of interferon and phagocytosis systems. Decreases the tonus of small intestine muscular system, increases the sensitivity to acetylcholine and barium chloride.

The preparation's prolonged use (aerosol, skin and mucous tunic smearing, bandages, compresses etc.) causes no toxic manifestations.

LD-50 at intraperitoneal introduction is 13.9 - 45.0 mg/kg for rats and 11.4 - 32.4 mg/kg for mice; that at enteral introduction is 133.0 - 319.0 mg/kg and 25.0 - 47.0 mg/kg, respectively. Daily 30-fold intraperitoneal use of the 1/10 - 1/16 LD-50 doses caused no complications or postmortem changes. No toxic manifestations were detected at aerosol use during 30-days daily course. Izatizon is non-toxic in doses recommended for use.

The preparation spectrum. Izatizon is efficient for prophylaxis and treatment of diseases caused by virus and virus-microbe associations. Its spectrum includes: herpes viruses, mixoviruses, including influenza virus A, A-1, B, C, herpes labiales, herpes zoster, Marek disease, poultry infectious laryngotracheitis, bronchial pneumonia of horses and calves, ectromelia and smallpox vaccine viruses, virus of horses' Venezuela encephalomyelitis, virus of pigs' enteritis, waterfowls' enteroviruses; virus, microbe-virus and fungus diseases of bees, silkworm and oak silkworm; poliomyelitis and lymphatic leukemia viruses of baboons, viruses of useful insects and fish, as well as microorganisms: streptococci, staphylococci, pneumococci, pathogenic and yeast-like fungi etc.

Indications for use.

Izatizon is recommended at:

- mass infectious virus diseases (influenza, AIDS, epidemic encephalitis etc.);
- virus hepatitis A, B, C;
- acute diseases of upper airways (rhinitis, laryngotracheitis, bronchitis, bronchopneumonia, acute respiratory virus infections – ARVI);
- lungs, bones and genitals tuberculosis;
- oral cavity diseases (glossitis, gingivitis, stomatitis, periodontitis, parodontosis);
- diseases of skin, glands and mucous tunic (herpes of skin and mucous tunic, including genitals; shingles, burns, erysipelas, festering wounds and trophic ulcers, abscesses, furuncles, carbuncles, mastitis, lymphadenitis, psoriasis, mycotic lesions);
- urological and gynaecological diseases (nephritis, endometritis, salpingitis, trichomoniasis, clamidiosis, erosions, pointed condyloma, prostatitis, prostate adenoma);
- diseases of cavities (peritonitis, pleurisy, cystitis, endometritis), joints (injuries, synoviites, arthrites, including virus non-specific infectious polyarthritis and psoriatic arthritis);
- cerebral affections (meningitis, encephalitis, infantile cerebral paralysis, disseminated sclerosis);
- pretumor and tumor diseases (wart, papilloma, melanoblastoma and other tumors);
- neuritis and neuralgias, myesities;
- allergic skin diseases (eczema, nettle-rash etc.);
- diseases of ENT organs (otitis, mastoiditis, tonsillitis, pharyngitis, larynx papilloma, nose polypus);
- haemorrhoids.

Way of use and doses.

Izatizon is used as aerosol (inhalations at influenza and upper airways diseases), 2-5 ml per one taking, 3-4 times a day, the course of treatment is 5-10 days depending on disease acuteness. Izatizon is also used locally, as tampons and turundas, soaked by 1-2 ml of the preparations, into each nostril, exposition time being 5-40 min depending on the process acuteness and individual sensitivity, during 3-6 days according to the prescriptions. Izatizon as ointment should be used in the same way. Izatizon for prophylaxis should be used similarly 1-2 times a day during 3 days in lower doses (0.5-1.0 ml per taking).

At skin and mucous tunic lesions the aerosol irrigations, smearings, applications and bandages should be used. The amount of the preparation used is not limited and depends on the affected area. The intervals depend on the prescription, but should be no less than 12 hours. The course of treatment is 10-15 days.

The liniment of 5-25 ml of izatizon into the affected area and bandages with the preparation for the night during 3-5 days are used against arthritis, neuritis, neuro- myesitis, lymphadenitis, mastitis, phlegmon, and neuralgia. At oral cavity lesions and tonsillitis izatizon is used as rinsing and smearing 2-4 times a day and as aerosol during 3-5 days, at otitis –gauze turundas, soaked in 1-2 ml of izatizone, every 12 hours. Duration of the course should be chosen according to the prescriptions, but no less than 5 days.

Izatizon could be used through rectum, 2-3 ml as microclysters using the syringe without needle and a nozzle made out of polyethylene tube, 4-5 cm long, or vaginally, as suppositories and vaginal beads, containing 0.35 ml of the preparation, three times a day and for night during 10-15 days. The tampons with izatizon could be used for night – one spoonful of the preparation per a tampon. This is the way of its use against systemic virus diseases, as well as prostate adenoma, pointed condyloma of external genitals, prostatitis, rectitis, haemorrhoids, vaginitis, and endometritis. At systemic lupus erythematosus and melanoblastoma izatizon should be used according to the mentioned scheme, externally as smearing and applications, through rectum, 2-3 ml as microclysters or suppositories and intranasally as aerosol or turundas during 30-45 days. After a month's break a second analogous course of treatment should be taken.

In case of stable forms of all the mentioned diseases, besides the external use, it is recommended to introduce izatizon rectally as microclysters (syringe plus rubber tube) after 48 hours, using 1-5 ml of preparation during 1-1.5 months. Usually three courses like this should be taken, the interval between them being 3-4 weeks.

At cystitis and endometritis the preparation is introduced into urinary bladder or uterine cavity, 10-15 ml each 48 hours until the disease is totally cured.

In cases of infectious enteritis, as well as all the peritonitis forms izatizon is recommended for internal use, 1 teaspoonful in the morning and in the evening before meal during 10-15 days, and rectal use at nights, 2-5 ml every other day.

The optimal izatizon dose for internal use and for the introduction into rectum as microclysters is calculated depending on the body weight – 0.075 ml of the preparation per 1 kg of the patient's weight. For example, people who weight 60 kg should take 4.5 ml etc.

The optimal dose for children of different age groups decreases correspondingly:

- from 1 to 7 years – the dose is 4 times decreased and comprises 0.0187 ml per 1 kg of body weight;
- from 7.5 to 12 years – the dose is 2 times decreased and comprises 0.0375 ml per 1 kg of body weight;
- after 13 years the dose is similar to that of adults.

Side-action: a short objectionable feeling on the treated skin or mucous tunics has been noticed for some of the patients. The contra-indications are not found. In case of unknown allergic reactions the treatment should be terminated.

Form of production: izatizon is produced in glass flacks of 100 ml, 50 ml and 10 ml and in aerosol balloons.

Suppositories, vaginal beads and ointments are produced in chemist's shops and hospitals or serially in case of necessity.

Conditions for storage: the preparation should be stored at dark place, at temperature 18-20 °C. The validity term is 5 years.