

ALEZAN CREAM FOR JOINTS

PACKAGE LEAFLET

for use of Alezan cream for joints in horses and dogs as an anti-inflammatory and chondroprotective drug product

Approved by: N. A. Vlasov, the Deputy Head of the Federal Service for Veterinary and Phytosanitary Surveillance

(Development organization: NVTs Agrovetzashchita Ltd., bld.1, 1, Kolskaia St., Moscow, 129329 Russia)

I. General

Trade name: Alezan cream for joints.

International nonproprietary name of the drug product: not defined.

Dosage form: cream for external use.

Alezan cream for joints contains the following active ingredient in 1 g of the cream: glucosamine hydrochloride – 10 mg, extract of devil's claw (*Harpagophytum procumbens* extract) – 5 mg, pine bud extract (*Pinus sylvestris* extract) – 5 mg, mugwort herb extract (*Artemisia vulgaris* extract) – 3,7 mg, fennel fruit extract (*Foeniculum vulgare* extract) – 3 mg, licorice root extract (*Glycyrrhiza glabra* extract) – 2,5 mg, mint leaf extract (*Mentha piperita* leaf extract) – 1,6 mg, thyme herb extract (*Thymus serpyllum* extract) – 1,5 mg, calendula flower extract (*Calendula officinalis* flower extract) – 0,5 mg, yarrow extract (*Achillea millefolium* extract) – 0,5 mg, horny goat weed extract (*Hypericum perforatum* extract) – 0,5 mg, chamomile flower extract (*Matricaria chamomilla* flower extract) – 0,4 mg, caraway fruit extract (*Carum carvi* extract) – 0,3 mg, rose fruit extract (*Rosa canina* extract) – 0,3 mg, celandine herb extract (*Chelidonium majus* extract) – 0,2 mg, and the excipients like: olive oil, glycerin, peg-8 stearate, collagen hydrolysate, mumijo, sodium hydroxide, phenoxyethanol, ethylhexylglycerin, carbomer and distilled water.

Appearance: the drug product represents a homogeneous creamy mass without additives of yellowish green to brownish green color.

The shelf life of the drug product shall be 18 months from the manufacturing date at compliance with the recommended storage conditions. Taking of the drug product after the expiration date is prohibited.

The drug product is packaged in polymeric vials and dosing vials of 100, 250, 500, 750 and 1000 g; polymeric tubes of correspondent capacity of 100, 200 and 250 g sealed with plastic screw caps. Tubes and vials of 100 g are individually packed into the cardboard boxes. Every consumer package contains the package leaflet for use of the drug product.

The drug product is stored tightly closed in the packaging provided by the manufacturer, in the place protected from direct sunlight and moisture, separately from foodstuff and fodders, at the temperatures from 5°C to 25°C.

Alezan cream for joints must be kept out of reach of children.

Unused drug product should be disposed in accordance with legal requirements.

Available without a veterinarian's prescription.

II. Pharmacological properties

Alezan cream for joints belongs to the drug products regulating metabolism within the cartilaginous tissue.

The drug product stimulates regeneration of the cartilaginous tissue, exerts anti-inflammatory and anesthetic action, facilitates prevention of the processes of cartilage destruction and stimulates the tissue regeneration.

Glucosamine, included into the composition of the drug product, possesses chondroprotective properties, participates at biosynthesis of proteoglycans and hyaluronic acid.

Glucosamine exerts a selective effect upon the joint cartilage, acting as a specific substrate and simulator of the synthesis of hyaluronic acid and proteoglycans, suppresses forming of peroxide radicals and ferments damaging the cartilaginous tissue (collagenases and phospholipases).

Harpagophytum procumbens extract, included into the composition of the drug product, exerts anti-inflammatory, analgesic and chondroprotective action revealed in inhibition of the inflammation mediators and mediators of cartilage destruction with the help of a set of biologically active ingredients that results in inhibition of the inflammatory processes.

Pinus sylvestris extract and *Artemisia vulgaris* extract exert local irritating, heating and anesthetic effect, stimulate peripheral blood circulation and decrease puffiness in tissues. *Foeniculum vulgare* extract possesses antiseptic and astringent properties.

Glycyrrhiza glabra extract soothes skin irritation, possesses encircling, softening and active anti-inflammatory effect, exerts spasmolytic action.

Mentha piperita leaf extract possesses soothing and anesthetic effect exerted upon the skin tissues due to a soft local irritating action, as well as improves capillary blood circulation.

Thymus serpyllum extract exerts tonic, softening, moisturizing, wound healing, antibacterial and anti-inflammatory action. *Calendula officinalis* flower extract contains carotenoids, flavonoids, phytosterines, antioxidants, saponines, vitamins, micro- and macroelements. It exerts anti-inflammatory and antibacterial action upon the skin, stimulates regeneration, recovers epidermis and increases the capillary strength. In addition to chamazulene, *Achillea millefolium* extract contains alkaloid achilleine, bornyl acetate, cineol, camphor, mineral salts, tannins, tars, phytosterines, carotene, vitamins C and K. It is used as an anti-inflammatory, healing, tonic, and anti-allergic drug product.

Hypericum perforatum extract possesses an anti-inflammatory, wound healing, spasmolytic, astringent, blood stopping and tonic action due to the effect of its active ingredients: flavones, antocyanins, etheric oils, tannins and resinous substances, mineral salts and organic acids.

Due to containing azulene, chamazulene, bisabolol and flavonoids *Matricaria chamomilla* flower extract possesses expressed anti-inflammatory, antiseptic, anesthetic and photo protective action.

Carum carvi extract contains etheric oil, flavonoids: quercetin and kaempferol, coumarins, umbelliferone and scopoletin. Possesses anti-inflammatory and antiseptic action.

Rosa canina extract enhances regeneration of tissues, decreases vascular permeability, takes part in carbon and mineral metabolism and possesses an anti-inflammatory action. *Chelidonium majus* extract possesses bactericide and anti-inflammatory effect at skin diseases. It normalizes water and lipid metabolism in the cells of skin.

In terms of the effect upon the animal body Alezan cream for joints can be referred to low hazardous substances

(hazard class 4 according to GOST 12.1.007-76), taken in recommended dosage exerts no resorptive toxic, skin irritating and sensibilizing effect; causes irritation while contacting mucosae.

III. Indications

Alezan cream for joints is administered to horses and dogs as an integral part of complex therapy at acute and chronic degenerative and dystrophic diseases of the musculoskeletal system in a localized form, including osteochondritis, arthritis, synovitis and bursitis, at exacerbations of chronic diseases of joints and tendons, for relieving of inflammatory processes at substantial loads, bruises, hematomae, myositis, straining and breakings of tendons. Contraindication for taking of the drug product includes increased individual sensitivity of the animal to the ingredients of the drug product. The drug product should not be applied to damaged skin and mucosa.

Alezan cream for joints is administered to animals externally 2 or 3 times daily, applying the cream in a thin layer on the preliminary cleaned from impurities dry undamaged skin of the problematic site rubbing it with light massage strokes until it absorbs completely. The hair in the site for administering the drug product in the long-haired dog breeds must be preliminarily cut. The procedure is performed during 15 to 30 days, after that the course of treatment is repeated after the 10-day break. Duration and number of the course of treatment depend on the progress of disease and determined by the attending veterinarian. In order to attain a more expressed and lasting effect air-tight bandage can be applied after rubbing of the drug product. After administering of the drug product it is recommended to let animals for rest during 20 to 30 minutes. Do not let animals licking out the drug product until it absorbs completely. No symptoms of overdosing are revealed at administration of Alezan cream for joints.

No particularities of action of the drug product at its first use and termination of use are revealed. The drug product as

allowed for administering to female animals during the periods of pregnancy and lactation. Non-compliance with the recommended scheme for proper use of the drug product must be avoided because it might result in decreasing of the therapeutic efficiency. At missing of scheduled application of the cream, the treatment must be renewed in the prescribed dosage and under the same treatment schedule.

At taking of Alezan cream for joints in accordance with this package leaflet no side effects and complications are observed, as a rule. In the cases of increased individual sensitivity of the animal to the drug product and occurrence of allergic reactions taking of the drug product is terminated and antihistamines and symptomatic therapy should be administered to the animal, if necessary.

Information about incompatibility of Alezan cream for joints with the drug products of other pharmacological groups and fodder additives is not available.

During and after administration of Alezan cream for joints all the animal products can be consumed without limitations.

IV. Personal preventive measures

The requirements set to personal hygiene and labor safety and health regulations imposed on handling drug products must be complied with while handling Alezan cream for joints.

Smoking, drinking and having meals is prohibited while handling the drug product. After handling the drug product wash your hands with soap and lukewarm water. People with hypersensitivity to the ingredients of the drug product must avoid direct contacting with Alezan cream for joints. It is prohibited to use empty package where the drug product has been contained for household purposes – the package must be disposed of with solid waste.

At incidental contact of the drug product with skin or eye mucosa rinse thoroughly with plenty of water. In the event of occurrence of allergic reactions or at incidental swallowing of the drug product consult the physician immediately (take away with you this package leaflet or the drug product label).

Marketing Authorisation No.: in Russia 77-3-14.15-3000 No. IIBP-3-14.15/02521 dated 19.02.2016

Name and address of the production site of the manufacturer of the drug product for veterinary use:

AVZ S-P LTD., 1, Tsentralnaia str., Sergiyev Posad, Moscow region , 141305 Russia.

Name and address of the organization authorized by the marketing authorization holder or owner of the drug product to accept claims from the consumers: AVZ S-P LTD., 1, Tsentralnaia str., Sergiyev Posad, Moscow region , 141305 Russia.

24-hour hotline: 8-800-700-19-93 (toll free in Russia).

See information on product conformity assessment at: www.vetmag.ru.

/AVZ
animal health/