APPROVED
Veterinary Medicinal Product Council
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Summary of Veterinary Product Characteristics

DECSA-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Decsa-TRV.

1.2 Veterinary Product Decsa-TRV is a hormonal veterinary medicinal product in the form of a solution for injection, has a clear liquid from colourless to light yellow, without impurities, each ml contains 4 mg of dexamethasone sodium phosphate and excipients - sodium metabisulfite, benzyl alcohol, polyethylene glycol, water for injection.

1.3 The veterinary medicinal product is packed in glass or polymer vials of appropriate capacity of 10, 20, 30, 50, 100, 200 and 400 ml, hermetically sealed with rubber stoppers and reinforced with aluminium caps with tamper-evident clips. Capping with other stoppers and caps is allowed, ensuring the tightness of the package.

1.4 Decsa-TRV is stored in a dry, dark place at temperatures from + 5 ° C to + 25 ° C. Shelf life is two years from the date of manufacture, provided that the storage conditions are observed. After opening the bottle, the veterinary medicinal product is stored for 28 days at a temperature from 5 ° C to 25 ° C.

After the expiration of shelf life unused veterinary medicinal product should be disposed in accordance with local requirement.

2. PHARMACOLOGICAL PROPERTIES

2.1 DECSA-TRV belongs to the group of synthetic glucocorticosteroids and has a potent anti-inflammatory, desensitizing effect and immunosuppressive activity.

2.2 Dexamethasone - a synthetic glucocorticosteroid (GCS), a methylated derivative of fluoroprednisolone, increases the sensitivity of beta-adrenergic receptors to endogenous catecholamines.

2.3 The mechanism of action of the hormone is to block the release of inflammatory mediators by eosinophils, including prostaglandins, which potentiate the inflammatory process, stimulate the biosynthesis of lipocortin with anti-oedematous activity, reduce the number of mast cells that produce hyaluronic acid, and reduce capillary permeability.

The main effect of dexamethasone on metabolism is associated with protein catabolism, an increase in gluconeogenesis in the liver, and a decrease in glucose disposal by peripheral tissues.

2.4 With parenteral administration of dexamethasone, the maximum plasma concentration is detected after 60 minutes. The therapeutic concentration in blood serum lasts up to 48 hours, depending on the type of animal. It is excreted from the body mainly with urine and bile. The bioavailability of dexamethasone when administered intramuscularly is 100%.

2.5 DECSA-TRV, according to the exposure degree to the body, is classified as low-hazard substances (hazard class 4 according to GOST 12.1.007-76).

3. INDICATIONS FOR USE

DECSA-TRV is administrated to live-stock and domestic animals as anti-inflammatory, anti-allergic, decongestant and gluconeogenetic agent in the treatment of post-traumatic oedema, arthritis, tenosynovitis, as well as acute mastitis and ketosis in cattle, allergic dermatitis and eczema in dogs and cats.

3.2 The veterinary medicinal product is administered once, intramuscularly as an anti-inflammatory and antiallergic agent in the following doses, in accordance with the table

Table - Veterinary medicinal product dosage

Target species	**Recommended dosage**
Horses, cattle	4-8.5 ml per 500 kg of animal weight

Calves, sheep, goats, pigs	0.15 -0.3 ml per 10 kg of animal weight
Dogs and cats	0.15-0.4 ml per 5 kg of animal weight, subcutaneous administration is allowed
If necessary, the administration can be repeated after 2 days- dogs, after 3-4 days -other animals.	
Cows	according to indications- 8-9 ml of the veterinary medicinal product per 500 kg of animal weight
Sheep, goats	Postpartum toxaemia and induction of parturition - - 4-4.5 ml per 50 kg of animal weight
Shock conditions	Slow intravenous administration of a ten-fold anti-inflammatory dose, if necessary, repeat after 8-12 hours

3.3 Contraindications. The use of the veterinary medicinal product is contraindicated in case of hypersensitivity to the veterinary medicinal product components. Must not be used in females' animals in the 3rd trimester of gestation.

3.4 Slaughtering of cattle, small ruminants and pigs for human consumption is allowed no earlier than 48 days, horses - 24 days after the last use of the veterinary medicinal product.

The meat of animals that were forcedly killed before the expiration of the specified period can be used as feed for carnivores.

3.5 Milk of dairy animals may be used for food purposes not earlier than 3 days after the last use of the veterinary medicinal product.

The milk obtained earlier can be used after boiling in animal feed.

4. PREVENTIVE MEASURES

4.1 Generally accepted personal hygiene measures and safety rules should be observed when working with this veterinary medicinal product.

5 CLAIMING PROCEDURE

5.1 In case of complications after the use of the veterinary medicinal product, its use is discontinued and the consumer should apply to the State Veterinary Institution on the territory of its location. Veterinary specialists of this institution study compliance with all the rules for the use of the veterinary medicinal product in accordance with the instructions. After the confirmation of a veterinary medicinal product adverse effect to the animal, the veterinary specialists take samples in the required amount for laboratory tests, at least three unopened vials of the veterinary medicinal product from the batches that caused the complication, a sampling report is drawn up and sent to the State Institution "Belarusian State Veterinary Center" (220005, Minsk, Krasnaya Str. 19-a, tel. 290-42-75) for confirmation of compliance with regulatory documents.

6 FULL NAME OF MANUFACTURER

6.1 Stovek, LLC, Republic of Belarus, 222660, Minsk Region, Stolbtsy, Zadvoryenskaya St., 2 .

The Summary of Veterinary Product Characteristics was developed by the employees of Stovek, LLC, (A.Yu. Finogenov, T.A. Soboleva, E.G. Finogenova). [Stamp]:

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