

Summary of Veterinary Product Characteristics
KETOPROFEN 10-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Ketoprofen10-TRV.

1.2 Ketoprofen 10-TRV is an anti-inflammatory veterinary product, solution for injection, clear colorless or slightly yellow solution without mechanical impurities, 1 ml contains 100 mg of ketoprofen and excipients - propylene glycol, benzyl alcohol, water for injection.

1.3 The product is packed in glass or polymer vials of 10, 20, 30, 50, 100, 200 and 400 ml, hermetically closed with rubber stoppers and tamper resistant aluminum caps. Capping with other stoppers is allowed, ensuring the container closure integrity.

1.4 Ketoprofen 10-TRV is stored in a dry, dark place at temperatures from plus 5°C to plus 25°C. Shelf life is two years from the date of manufacture, subject to storage conditions. The shelf life once opened is 7 days at a temperature of plus 5°C to plus 25°C.

2. PHARMACOLOGICAL PROPERTIES

2.1 Ketoprofen 10-TRV is non-steroidal anti-inflammatory veterinary product.

2.2 Ketoprofen is a propionic acid derivative and has a pronounced anti-inflammatory, analgesic and antipyretic effect, inhibits platelet aggregation.

2.3 The mechanism of action is based on inhibition of the activity of COX, the main enzyme of the metabolism of arachidonic acid, and is a precursor of prostaglandins and plays a major role in the pathogenesis of inflammation and pain. The pronounced analgesic effect of ketoprofen is due to two mechanisms: peripheral (indirectly, through suppression of prostaglandin synthesis) and central (due to inhibition of prostaglandin synthesis in the central and peripheral nervous system, as well as the effect on the biological activity of other neurotropic substances that play a key role in the release of mediators in the spinal cord). In addition, ketoprofen stabilizes lysosomal membranes, causes a significant inhibition of neutrophil activity in animals with arthritis, and suppresses platelet aggregation.

In horses, ketoprofen counteracts the effects of endotoxin and prevents the intestinal spasm caused by bradykinin.

2.4 In parenteral administration of the veterinary product, the maximum concentration of ketoprofen in the blood plasma of animals is observed 30-40 minutes after injection. The bioavailability of ketoprofen, depending on the animal species, varies from 85% to 100%. The veterinary product is excreted in the form of metabolites, mainly with urine.

2.5 Ketoprofenum 10-TRV, according to the degree of the exposure, belongs to low-hazard substances (hazard class 4 according to GOST 12.1.007-76).

3. DOSAGE AND INDICATION

3.1 Ketoprofen 10-TRV is used in cattle, pigs and horses as an anti-inflammatory, analgesic and antipyretic agent for acute and chronic diseases of the musculoskeletal system (arthrosis, arthritis, dislocations, trauma, herniated discs, etc.), to relieve inflammatory and pain reactions after surgery, as well as in horses for the symptomatic treatment of colic.

3.2 The veterinary product is administered intramuscularly or intravenously once a day in the following doses, in accordance with the table:

Table - Doses of the veterinary product

Animal species	Recommended dose
cattle	intravenously or intramuscularly at a dose of 3 ml per 100 kg of animal weight (3 mg of active substance per 1 kg of animal weight) for 1-3 days

horses	intravenously in the treatment of the musculoskeletal system at a dose of 1 ml of the veterinary product per 45 kg of animal weight (2.2 mg of active substance per 1 kg of animal weight) for 3-5 days
	intravenously for symptomatic treatment of colic in a dose of 1 ml of the veterinary product per 45 kg of animal weight, once
pigs	intramuscularly at a dose of 3 ml per 100 kg of animal weight (3 mg of active substance per 1 kg of animal weight) for 1-3 days

3.3 Adverse effects, except for cases of individual hypersensitivity to the components of the medicinal product, were not identified. If symptoms of an allergic reaction appear, the veterinary product is discontinued and, if necessary, symptomatic therapy is started.

In case of an overdose of the veterinary product, animals may experience vomiting, excretion of black feces, respiratory depression, convulsions.

3.4 The use of the veterinary product is contraindicated in case of hypersensitivity to the components of the veterinary product, gastric and duodenal ulcers, hemorrhagic syndrome, severe renal and hepatic failure. It must not be used in animals during pregnancy.

3.5 Must not be concomitantly used with other non-steroidal anti-inflammatory veterinary products, glucocorticoids and diuretics. Do not mix with other medicines in the same syringe.

3.6 It is possible to use the veterinary product in animals during lactation

3.7 Slaughter of cattle for meat is allowed no earlier than 5 days, pigs - 4 days after the last administration of the veterinary product.

The meat of animals, forcibly killed before the expiration of the specified period, can be used to feed carnivores.

3.8 Milk of dairy animals during and after the administration of the veterinary product may be used without restrictions.

4. PREVENTIVE MEASURES

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

5 CLAIMING PROCEDURE

5.1 In case of complications after the use of the veterinary 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 product in accordance with the instructions. After the confirmation of a veterinary 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 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).

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<p style="text-align: center;">Department of Veterinary and Food Control of the Ministry of Agriculture and Food of the Republic of Belarus Veterinary Medicinal Product Council Approved Chairman [Signature] Secretary [Signature] Expert [Signature] 12.09.2019 Minutes No. 103</p>
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