

APPROVED

Veterinary Medicinal Product Council
Minutes No. 104 dated October 25, 2019

Summary of Veterinary Product Characteristics
OXYTOCIN 10 ME-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Oxytocin 10 ME-TRV.

1.2 Oxytocin 10 ME-TRV is a hormonal preparation, dosage form - solution for injection, colorless transparent liquid, without impurities, 1 ml contains 10 IU of oxytocin and excipients - 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 Oxytocin 10 ME-TRV is stored with caution (under the requirement of the list B): 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 and transportation conditions. The shelf life once opened is three days at a temperature of plus 5°C to plus 25°C.

2. PHARMACOLOGICAL PROPERTIES

2.1 Oxytocin 10 ME-TRV belongs to the pharmacological group: hormones and their antagonists.

2.2 Oxytocin is a synthetic analogue of the peptide hormone of the posterior pituitary gland. Under the influence of oxytocin, the permeability of cell membranes increases, the resting potential decreases, and the excitability of the muscles of the uterus increases. It has a stimulating effect on the smooth muscles of the uterus, increases the contractility of the myometrium, increases the frequency and amplitude of contractions, in high concentrations helps to increase the tone of the uterus.

2.3 Oxytocin stimulates milk secretion by increasing prolactin production by the anterior pituitary gland. Reduces myoepithelial cells around the alveoli of the mammary gland, stimulates the flow of milk into the large ducts and sinuses.

The drug is practically devoid of vasoconstrictor and antidiuretic action (only in high doses), does not cause contraction of the muscles of the bladder and intestines.

2.4 With subcutaneous and intramuscular administration, the effect of oxytocin on the smooth muscles of the uterus shows within 1-3 minutes, the duration of the pharmacological effect is from 20 to 30 minutes, with intravenous administration in 0.5-1 minutes.

2.5 The drug is inactivated in the liver and kidneys. A small amount of oxytocin is excreted in the urine. Half-life in animals is 5-7 minutes

2.6 Oxytocin 10 ME-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 Oxytocin 10 ME-TRV is used in agricultural and domestic animals with weak labor, uterine bleeding, retention of the placenta, endometritis, mastitis and reflex agalactia.

3.2 The drug is administered subcutaneously, intramuscularly, intravenously (slowly), and, if necessary, in combination with novocaine epidurally in the following doses, in according to the table.

Table - Doses of the drug

Animal species	Route of administration and recommended dose, IU (UNIT) / animal		
	subcutaneously or intramuscularly	intravenously (infusion)	epidural
mares, cows	30-60	20-40	15-30
sows	30		10-15
weighing up		20	

to 200 kg			
goats, sheep	10-15	8-10	
dogs	5-10	2-7	
cats	3	2	2

3.3 Violation of the recommended regimen of the drug should be avoided in order to avoid a decrease in its effectiveness, or the occurrence of adverse effects.

3.4 Adverse effects and complications after administration of the drug with the correct doses have not been established. When using the drug in excessive doses or hypersensitivity to oxytocin, excessive labor activity (hypertonicity of the uterus) may occur. In these cases, the administration of the drug is discontinued, an isotonic solution of sodium chloride and glucose must be administered intravenously.

3.5 The use of the drug is contraindicated in case of hypersensitivity of animals to the components of the drug, during obstetrics in cases of a large fetus, deformity, in case of misalignment of the fetus, twisting of the uterus, during pregnancy and a closed cervix, as well as multiple pregnancies and the presence of scars on the wall of the uterus.

3.6 Oxytocin is incompatible with fibrinolysin, norepinephrine, meterazine.

3.7 Livestock products during the period of application of the drug are used without restrictions.

4 PREVENTIVE MEASURES

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

5 CLAIMING PROCEDURE

5.1 In case of complications after the use of the drug, 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 drug in accordance with the instructions. After the confirmation of a drug adverse effect to the animal, the veterinary specialists take samples in the required amount for laboratory tests, at least three unopened vials of the drug 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>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] 25.10.2019 Minutes No. 104</p>
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