APPROVED
Deputy Head of Federal Service
for Veterinary and Phytosanitary Surveillance
(Rosselkhoznadzor)
(signed)
N.A.Vlasov
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SEAL:
Ministry of Agriculture of the Russian Federation
Federal Service for Veterinary and Phytosanitary Surveillance

INSTRUCTION FOR USE
the drug Giprolam
for preventing postpartum endometritis in cows

(developer organization: "Biotechagro" LLC, Timashevsk, Krasnodar Region)

I. GENERAL

1. Trade name of the medicinal product: Giprolam.

International nonproprietary, or grouping, or chemical name of the medicinal product: not assigned.

2. Dosage form is a suspension for intrauterine application.

Giprolam ismanufactured from living cultures of strains *Lactobacillus fermentum* 44/1 (RNCIM (Russian National Collection of Industrial Microorganisms) B-2940) and *Lactococcus lactis subsp. Lactis* 57_4 (RNCIM B-3145) with addition of excipients – glycerin (20%), potato starch (2.4%), glucose (1.6%), Broth nutritious GRM (1.2%), corn extract (0.87%), whey (0.45%) and water (72.7%).

3. By its appearance, Giprolam is a light-brown suspension, of slightly sour smell with the gray sediment easily broken by shaking.

Shelf life of the drug – 6 months since the manufacturing date at the temperature of minus 18°C, 45 days since the date of defrosting at the temperature from + 2° up to + 10°C. After opening, use within three hours.

A single defrosting of the drug is admitted for transportation and storage at the temperature from + 2° up to + 10°C for 9 days with subsequent freezing and storage at the temperature of minus 18°C until the expiration date.

Do not use the drug after the expiration date.

4. Giprolam is packaged in 100.0 cm^3 (1-dose) sterile polymeric containers for infusion solutions sealed with sterile polymeric stoppers or in sterile glass vials sealed with sterile rubber stoppers pressurized with aluminum caps, or in sterile tubes made of polymeric materials sealed by heat sealing. Each unit of consumer package is provided with instructions for use. Secondary consumer packaging is not provided.

For transportation, Giprolam is packaged in a box made of corrugated cardboard or in a box with a lid made of polystyrene.

5. The drug is stored in manufacturer's packaging in a freezer at minus 18°C, after defrosting – in a clean, dry, dark place at the temperature from minus 2° to 10°C.

Transportation of the drug is done at the temperature of 2° to 10°C in a clean, dry, dark place.

6. Giprolam shall be stored in places inaccessible to children.

7. Polymer containers for infusion solutions, bottles and tubes with the drug without labels, with expired shelf life, with disruption of integrity and/or capping tightness, with a changed color and/or consistency of the contained, with presence of impurities, are subject to rejection with subsequent disposal as household waste.

8. Giprolam is available without a veterinarian's prescription.

II BIOLOGICAL PROPERTIES

9. Giprolam is related to probiotic drugs.

The mechanism of drug effect is facilitated by presence in its composition of live probiotic cultures *Lactobacillus fermentum* 44/1 and *Lactococcus lactis subpsp.lactis* 57_4. Probiotic microorganisms are able to survive in the genitourinary tract in cows and have an antagonistic effect on the opportunistic microflora penetrating into the vagina and uterus. The drug prevents the development of postpartum endometritis in cows, reduces the length of the service period.

10. 1.0 cm^3 of the drug (0.01 dose) contains: live cultures of lactic acid bacteria *Lactobacillus fermentum* 44/1 (strain RNCIM B-2940) - at least $5x10^7$ CFU and *Lactococcus lactis subsp. Lactis* 574 (strain RNCIM B-3145) - not less than $1x10^7$ CFU.

III PROCEDURE OF USE

11. Giprolam is used for prevention of postpartum endometritis in cows.

12. Contraindications for drug use is not established.

13. Giprolam is used in the following schemes:

Scheme 1. Giprolam is used intravaginally and endometrially by 100.0 cm^3 (one dose) three times with Janet syringe and gynecological pipette. The course of prevention is made of 3 administrations. The first drug administration – intravaginally at 10-5 days before calving, the second – endometrially not later than 12 hours after calving (preferably in the first hour after calving), the third – endometrially in 24 hours after the second administration.

Scheme 2. Giprolam administered endometrially in the dose of 100.0 cm^3 (one dose) in the first hours after calving (within 12 hours after calving), the second drug administration – in 24 hours after the first administration.

Before drug administering, sanitary treatment of the external genitals is done.

Before use, the drug is shaken and heated to the temperature of 37-38°C.

On Days 3-7 after intrauterine drug administering, from the external genitalia fluid of dark brown color can discharge without sanious odor. In the case of exudate discharge with sanious odor, the generally accepted medical therapy is done.

14. No symptoms of toxicosis or other adverse reactions due to Giprolam overdosing were recorded.

15. Features of drug effect after the first administration or its cancellation were not established.

16. The drug can be used without restrictions in pregnant animals and animals during lactation. The drug does not have a negative effect on the offspring of animals.

17. Special measures when skipping one or more doses of the drug are not provided, the interrupted prevention course shall be continued.

18. When using the drug in accordance with this instruction, side effects and complications were not detected.

19. The use of Giprolam along with antibiotics and sulfonamides reduces the therapeutic effect of the drug.

20. Livestock products after Giprolam administration can be used without limitations.

IV. PERSONAL PREVENTION MEASURES

21. While handling Giprolam, the general rules of personal hygiene and safety provided when dealing with medical drugs of veterinary use shall be followed. Special precautions when working with the drug are not required.

22. When working with the drug, eating, drinking, or smoking are prohibited. After work, wash your hands with soap. While working with the drug, the usual remedies provided for handling veterinary drugs in gynecology are used (gown, cap, rubber gloves). Special personal protective equipment is not required when working with the drug.

23. In case of contact with the skin and/or mucous membranes, it is recommended to wash them with a plenty of tap water. In case of accidental ingestion antidote is not required.

With approval of these instructions, the Instruction for Use for Giprolam approved by the Deputy Head of the Rosselkhoznadzor on January 22, 2014, shall be cancelled.

The names and addresses of production facilities of the manufacturer of the drug for veterinary use	"Biotechagro" LLC 68 Vybornaya Str., Timashevsk, Krasnodar Region 352700
Name, address of the organization authorized by the holder or the owner of registration certificate for accepting claims from consumers	"Biotechagro" LLC 68 Vybornaya Str., Timashevsk, Krasnodar Region 352700

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General Director
of "Biotechagro" LLC V. A. Babarykin