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

INSTRUCTION FOR USE
of Prolam medicinal drug for dysbacteriosis prevention and increase of natural resistance of agricultural animals, including birds and fish

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

I. GENERAL

1. Trade name of the drug: Prolam

International nonproprietary, or grouping, or chemical name of the medicinal drug: Prolam for the prevention of dysbacteriosis and increasing the natural resistance of farm animals, including birds and fish

2. Dosage form is a suspension for oral administration.

Prolam is made from alive cultures of *Lactobacillus delbrueckii subsp.bulgaricus* (RNCIM (Russian National Collection of Industrial Microorganisms) B-5788), *Bacillus sporothermodurans* 43s (RNCIM B-3235), Streptococcus lactic acid producer *Lactococcus lactis subsp.Iactis* 57_4 (RNCIM In-3145) and *Lactococcus lactis subsp.Lactis* 170_4-5 (RNCIM B-3192), *Bifidobacterium Bifidobacterium animalis* 83 (RNCIM AC-1248), with the addition of auxiliary substances – milk serum (3.35 %), corn extract (1.3%) and water (93.7 %).

3. In appearance, Prolam is a suspension of cream or light brown, of slightly acidic smell with an easily broken gray sediment when shaken.

Shelf life - 3 months since the date of manufacturing, subject to storage and transportation conditions. Shelf life after the first opening of the package - no more than 24 hours. Do not use the drug after the expiration date.

4. Prolam is packaged in 1.0 dm^3 (1000 doses); 1.5 dm^3 (1,500 doses); 5.2 dm^3 (5,200 doses); a 10.0 dm^3 (10,000 doses) in sterile bottles made of polymer material and is hermetically sealed with sterile plastic screw caps with tamper-evident. 1.0 dm^3 and 1.5 dm^3 plastic bottles are packed in corrugated cardboard boxes. Each packaging unit is provided with instructions for use.

5. Prolam is stored and transported in a dry, protected from light place at the temperature from 2°C to 10°C.

6. Prolam shall be stored out of reach of children.

7. Drug bottles without labels, expired bottles, bottles with disruption of integrity and/or capping, 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. Prolam is available without a veterinarian's prescription.

II BIOLOGICAL PROPERTIES

9. Prolam is related to probiotic drugs.

The mechanism of drug effect is facilitated by presence in its composition of live probiotic cultures of lactic acid bacteria and lactococci, as well as bifidobacteria - producing biologically active compounds that activate the processes enhancing non-specific immunity and contributing to normalization of intestinal microbiocenosis, reducing the risk of diarrheal syndrome.

10. One dose (1.0 cm^3) contains: live cultures of lactic acid bacteria *Lactobacillus delbrueckii subsp.bulgaricus* (strain RNCIM B-5788) and *Bacillus sporothermodurans* 43c (strain RNCIM B-3235), Streptococcus lactic acid producer *Lactococcus lactis subsp.Lactis* 57_4 (strain RNCIM B-3145) and

Lactococcus lactis subsp.Lactis 170_4-5 (strain RNCIM B-3192) - not less than $2.5x10^7$ CFU each, as well as bifidobacteria *Bifidobacterium animalis* 83 (strain RNCIM B -1248) - not less than $1x10^7$ CFU.

III PROCEDURE OF USE

11. Prolam is used to prevent dysbacteriosis and increase natural resistance in farm animals, including birds and fish.

12. Contraindications for drug use have not been established.

13. The drug is administered to animals orally individually or in a group method in pure form or mixed with milk, colostralmilk, water or fodder.

Recommended single daily prophylactic doses for animals according to the following scheme:

- piglets, since Day 1 to Day 7, on Days 15 - 21, 29-35, 43-49 and 57 - 60 - 3 doses (3.0 cm^3) per animal;
- pigs, from Day 61 to Day 67, on Days 75 - 81 , 89- 95, 103-109 and 117 - 120 - 5 doses (5.0 cm^3) per animal;
- pregnant sows, twice - for 30 - 20 and 10 days before the term of farrowing -10 doses (10.0 cm^3) per animal;
- lambs and kids, since Day 1 to Day 21 -3 doses (3.0 cm^3) per animal;
- calves, since Day 1 to Day 21 - 15 doses (15.0 cm^3) per animal.

The bird is prescribed the drug by a group method with water or fodder, as well as in aerosol and coarse spraying form (spray method).

Recommended prophylactic doses of Prolam drug, at the rate of once a day, according to the following scheme:

- broiler chickens, since Day 1 to Day 14, on Days 22 - 28 and 36 - 0.1 dose (0.1 cm^3) per bird;
- chickens of egg-laying breeds, since Day 1 to Day 14, on Days 22 - 28 – 0.1 dose (0.1 cm^3) per bird;
- goslings, since Day 1 to Day 14, on Days 22 - 28 and on Day 36 - 0.2 doses (0.2 cm^3) per bird;

Adult poultry under stress periods are prescribed Prolam daily for 7 days at the rate of 2 doses (2 cm^3) per 1 liter of drinking water per day.

Treatment of chickens and goslings with drug aerosol is done in hatchery for an hour before new-born chickens picking up (exposure time - 5 minutes), at the rate of 15 doses (15 cm^3) of the drug per 1m^3 of hatchery volume.

Treatment of chickens and goslings before transportation to Growing Area is done in a transport container in the hatchery, by spray method by spraying birds with coarse particle aerosol using a sprayer, Prolam consumption makes 0.25 dose (0.25 cm^3) per 1 chick.

The drug is prescribed to fish by group method with animal feed. The recommended scheme of the drug prophylactic dose at the rate of:

- carp and sturgeon since Day 1 to Day 7, on Days 15-21 and 29 - 35 -3 doses (3.0 cm^3) per 1 kg of animal feed (the drug is sprayed on feed);

The drug is thoroughly shaken before use.

14. Toxicosis symptoms or other adverse response to Prolam overdosing have not been revealed.

15. No peculiar features for the first drug intake or its cancellation were established.

16. The drug can be used without restriction in pregnant animals, in animals during lactation, the drug does not have any negative effects on the offspring of animals.

17. Special activities when skipping one or more drug doses are not provided, the interrupted prevention course is continued.

18. When using the drug in accordance with this instruction, no side effects and complications were registered.

19. Use of Prolam simultaneously with antibiotics and sulfonamides reduces the therapeutic effect of the drug.

20. Livestock, poultry and fish products after Prolama application can be used without restrictions.

V PERSONAL PREVENTION MEASURES

21. Handling the drug shall comply with the rules of personal hygiene and safety provided when working with drugs for veterinary use. No special measures for personal prevention while handling the drug are required.

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

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

With the approval of these instructions, the instructions for use of Prolam drug approved by the Deputy Head of the of Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor) on August 28, 2010 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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