

DIRECTIONS FOR USE

Monosporin for Dysbacterioses Prevention and Enhancement of Natural Resistance
of Livestock Including Poultry
(developed by "Biotekhagro" LLC, Timashevsk, Krasnodar Territory)

I. GENERAL INFORMATION

1. Trade name: Monosporin

International nonproprietary name: *Bacillus subtilis*

2. Monosporin pharmaceutical form: suspension for oral use containing live spore-forming bacterium *Bacillus subtilis* 945 (C-5225) in the culture medium. One cubic centimeter of the product contains at least 1×10^8 colony forming units (CFU) of the spore-forming bacteria.

The colour of Monosporin liquid suspension is from beige to brown.

3. Monosporin packaging: 0.4; 1.0; 2.0 dm³ sterile plastic containers for infusion solutions, 0.4 dm³ glass jars or bottles. Polymer containers are sealed with sterile special polymer stopper; cans or bottles are sealed with sterile rubber stopper and crimped aluminum cap.

Every unit of consumer packaging is provided with instructions for use.

Shelf life: 6 months from the manufacture date, subject to the conditions of storage and transportation.

Monosporin shall not be used after the expiry date.

4. The preparation is stored in the original container in a dry, clean, dark room at a temperature of 2° to 10°C.

Keep out of the reach of children.

5. Preparation polymer containers, jars or bottles without label, with expired shelf life, damaged package, containing impurities, discolored or with sedimentation, unused for 3 days after opening the primary packaging are subject to rejection and subsequent disposal with household waste.

II. BIOLOGICAL PROPERTIES

6. The bacteria *Bacillus subtilis*, as a part of the preparation, release biologically active substances activated under the influence of digestive processes increasing non-specific immunity, resulting in normalized intestine microbiocenosis, thus improving the efficiency of livestock rearing and stock viability.

III. APPLICATION

7. Monosporin is used to prevent dysbacterioses and improve the natural resistance of livestock including poultry.

8. No contraindications have been established.

9. The preparation is prescribed for oral use by the animals individually or in groups via drinking (with milk, colostrum, water) or with food. Shake the container before use.

The recommended daily preventive rate for:

- Calves from 1 to 8 and 26 to 30 days of life: 4.0 cm³ per animal;
- Pigs from 1 to 8 days life: 2.0 cm³ per animal;
- Piglets up to 3 days before weaning and 3 days after weaning: 2.0 cm³ per animal;
- Sows 10 days before farrowing for 10 days: 10.0 cm³ per animal;
- Sows 3 days before weaning for 3 days: 10.0 cm³ per animal;
- Broilers from 1 to 13 and from 30 to 35 days of life: 3.0 cm³ per 100 heads;
- Egg laying hens and meat cross, ducks with 130 days of life for 10 days: 20.0 cm³ per 100 heads.

10. No adverse reactions have been identified in case of Monosporin overdose.

11. No specific impact of the preparation has been identified at its first administration or cancellation.

12. No special measures shall be provided when skipping one or more doses, the interrupted course of prophylaxis can be continued.

13. No side effects or complications are observed while applying the preparation in accordance with this instruction.

14. Monosporin is not recommended for use in conjunction with antibiotics.

15. No restrictions are applicable to meat and poultry products sales after Monosporin administration.

IV. PERSONAL SAFETY MEASURES

16. Good personal hygiene and safety rules shall be observed when dealing with preparations for veterinary use.

17. Special precautions for working with the preparation are not required.

18. Drinking, smoking and eating when working with the preparation is forbidden. Wash hands with soap and water after work. In case of skin and / or mucous membranes contamination wash them with plenty of tap water.

19. The company manufacturer: "Biotekhagro" LLC
(352700, Krasnodar Territory, Timashevsk, 68 Vybornaya str.)

Directions for use are developed by "Biotekhagro" LLC (Timashevsk)

The approval of this document supersedes "Instruction on Monosporin Use" approved by the Deputy Head of the Rosselkhoznadzor on 12 of May, 2008.

Recommended for registration in the Russian Federation by Federal State Institution "All-Russian State Research Institute of Control, Standardization and Certification of Veterinary Preparations" (VGNKI)

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