

APPROVED
Deputy Head of Federal Service
for Veterinary and Phytosanitary Surveillance
(Rosselkhoznadzor)
(signed)
G.A.Nepoklonov
November 15, 2013
SEAL:
Ministry of Agriculture of the Russian Federation
Federal Service
for Veterinary and Phytosanitary Surveillance

INSTRUCTION FOR USE
of Monosporin for dysbacteriosis prevention
and increase of natural resistance of animal organisms, including birds
(developer organization: "Biotechagro" LLC, Timashevsk, Krasnodar Region)

I. GENERAL

1. Trade name: Monosporin

International nonproprietary name: *Bacillus subtilis*

2. Dosage form is suspension for oral administration

Monosporin contains live spore-forming bacteria *Bacillus subtilis* 945 (B-5225) in the culture medium. In 1 cm³ of the drug at least 1x10⁸ CFU (colony forming units) of spore-forming bacteria are contained.

Monosporin is a liquid suspension coloured from beige to brown.

3. Monosporin is packaged per 0.4; 1.0; 2.0 dm³ in sterile polymer containers for infusion solutions, and per 0.4 dm³ in glass jars or bottles. Polymer containers are sealed with a special polymer sterile stopper, cans or bottles are sealed with a sterile rubber stopper and compressed with an aluminum cap.

Each unit of consumer packaging is provided with Instructions for Use.

Shelf life of the drug – 6 months since the manufacturing date subject to observation of storage and transportation conditions.

Monosporin shall not be used after the expiration date.

4. The pharmaceutical drug shall be stored in manufacturer's packaging in a dry, clean premise protected from light at the temperature from 2° to 10°C.

Monosporin shall be stored out of reach of children.

5. Polymer containers, glass jars or bottles with the pharmaceutical drug without marking, expired, with disruption of integrity and/or tightness, drug package containing impurities, with a changed color, as well as drug residuals unused within 3 days after opening the original packaging are subject to rejecting followed by disposal with household waste.

II. BIOLOGICAL PROPERTIES

6. Bacteria *Bacillus subtilis* being a part of the drug emit biologically active substances, under the influence of which the digestion processes are activated, nonspecific immunity is enhanced, as a result of which the intestinal microbiocenosis is normalized, and the survival rate of livestock and efficiency of young animals rearing increase.

III PROCEDURE OF USE

Monosporin is used for prevention of dysbacteriosis and increase of natural resistance of animals, including birds.

8. Contraindications have not been found.

9. The drug is prescribed to animals orally, individually or by group method with water (milk, colostrum milk, water) or fodder. The drug shall be shaken before use.

Recommended single daily prophylactic doses:

- calves, since Day 1 up to Day 8 and from Day 26 to Day 30 - 4.0 cm³ per animal;

- piglets, since Day 1 up to Day 8 - 2.0 cm³ per animal;

- piglets, 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 piglets weaning, for 3 days - 10.0 cm³ per animal;
 - broiler chickens since Day 1 up to Day 13 and from Day 30 to Day 35 - 3.0 cm³ per 100 heads;
 - laying hens of egg and meat crosses, ducks since Day 130 of life, for 10 days - 20.0 cm³ per 100 heads.
10. No adverse reactions were detected for Monosporin overdosing.
 11. No peculiar features for the first reception of the drug or its cancellation were established.
 12. Special activities when skipping one or more drug doses are not provided, an interrupted prevention course is continued.
 13. When using the drug in accordance with this instruction, no side effects and complications were registered.
 14. Monosporin is not recommended for joint use with antibiotics.
 15. Livestock and poultry products after the drug use shall be sold without restrictions.

IV PERSONAL PREVENTION MEASURES

16. Handling the drug shall comply with the rules of personal hygiene and safety provided when working with drugs for veterinary use.
17. No special measures for personal prevention while handling are required.
18. While handling the drug eating, drinking, or smoking are prohibited. After work, wash your hands with soap. In case of contact with the skin and/or mucous, it is recommended to wash them with a plenty of tap water.
19. Organization-manufacturer of "Biotechagro" LLC
(68 Vybornaya Str., Timashevsk, Krasnodar Region 352700)

Instructions for Use have been developed by "Biotechagro" LLC (Timashevsk, Krasnodar Region)

With approval of these instructions, the Instruction for Use of Monosporin approved by the Deputy Head of the Rosselkhoz nadzor of May 12, 2008, loses its effect.

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

Registration certificate number: 02-1-26.13-1668№ПБП-1-4.7/02099

General Director
of "Biotechagro" LLC

V. A. Babarykin