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10-04-2017  
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## INSTRUCTION

for use of the veterinary drug  
SEX BARRIER® drops for dogs  
for sexual heat control in female and male dogs

((Developer: LLC “RESEARCH AND PRODUCTION COMPANY "SKIFF",  
20, bldg 3, Nauchny proezd, Moscow, 117246)

### I. General Information

1. Trade name: SEX BARRIER® drops for dogs (SEX BARRIER® guttae pro canum).

Generic name: meprenol acetate and ethinyl estradiol.

2. Pharmaceutical form: oral drops.

SEX BARRIER® drops for dogs are available in two dosages containing in 1 ml the following active substances:

“for female dogs”: water-soluble mepregenol acetate – 2.00 mg and ethinyl estradiol – 0.02 mg;

“for male dogs”: water-soluble mepregenol acetate – 6.00 mg and ethinyl estradiol – 0.30 mg.

SEX BARRIER® drops for dogs contain as excipients: olive oil.

3. The drug is clear liquid of a light yellow, greenish yellow or golden yellow color.

The shelf life of the drug is 2 years from the date of manufacture subject to storage conditions.

Do not use SEX BARRIER® drops for dogs after the expiration date.

4. SEX BARRIER® drops for dogs are available in polyethylene vials with dispenser tips containing 2, 3 and 5 ml of the drug. The polyethylene vial is corked with a screw-on tamper-evident cap, packed in a blister and individually packed in cardboard boxes package insert.

5. Store the drug in the sealed original packaging, in a place protected from direct sunlight, separate from food and feed, at a temperature of 0 to 25 °C.

6. Store SEX BARRIER® drops for dogs out of the reach of children.

7. Any unused drug is disposed of in accordance with the law requirements.

8. Prescription status: over-the counter product.

### II. Pharmacological Properties

9. Pharmacotherapeutic group: hormones and their antagonists.

10. SEX BARRIER® drops for dogs are a bi-hormonal contraceptive drug containing hormones as active substances: gestagen – water-soluble meprenol acetate and estrogen – ethinyl estradiol.

Water-soluble meprenol acetate and ethinyl estradiol, acting on the hypothalamic-pituitary system of animals, reduce the secretion of gonadotropic hormones (FSH and LH) from the hypophysis. This results in inhibition of folliculogenesis in the ovaries and cessation of ovulation of follicles.

Ethinyl estradiol in combination with water-soluble meprenol acetate enhances the contraceptive effect by changing the biological properties of the vaginal environment, increases the viscosity of the cervical mucus, which inhibits sperm motility, and changes in the uterine endometrium prevent the implantation of the fertilized ovum. In male dogs, the level of testosterone and, consequently, sexual activity decreases.

The active substances of the drug are well absorbed in the intestine and, after biotransformation in the liver, are completely excreted in urine as metabolites within 48 hours.

SEX BARRIER® drops for dogs in terms of level of effects on the body belong to low-hazard substances (Hazard Class 4 according to GOST 12.1.007-76), the drug does not adversely affect the body of pets when used in the recommended doses.

### III. Treatment

11. SEX BARRIER® drops for dogs bi-hormonal contraceptive drug is intended for female dogs for sexual heat control (interruption and delay of estrus), and for preventing unwanted pregnancy; for male dogs for sexual heat control and control of associated aggressive behavior.

12. The contraindications of the drug include Greyhounds, pregnant and lactating female dogs, prepubescent animals, neoplasms of the mammary gland, diseases of the genital organs, diabetes mellitus and kidney stone disease.

13. The drug is administered orally by dripping onto the base of tongue, nose, or in feed. The dosage depends on the weight of the pet and the purpose of use (see Table 1):

Table 1

Pet type	Purpose of the drug		Pet weight	Dosage	Course of use	Start of intake	Notes
Female dogs	Sexual control	heat	Interruption of estrus	Below 5 kg	1 drop	twice per day with an interval of 12 hours during 5-7 days	1. The estrus is stopped after a full course of use. 2. In some cases, the use of the drug is extended until the termination of estrus. 3. It is recommended that estrus should be interrupted no more than 1 time per year.
		5.1 – 10 kg		2-4 drops			
	10.1-30 kg	5-8 drops					
		Delay of estrus	More than 30 kg	9 + 1 drop for each subsequent 5 kg of body weight		7-14 days before supposed estrus	1. Makes it possible to delay estrus for about 20-40 days. 2. It is recommended that estrus should be delayed no more than 2 time per year.
	Prevention of pregnancy	of unwanted				Twice with an interval of 24 hours	Not later than 24 hours after mating A later administration of the drug significantly reduces the effect of treatment.

Male dogs	Sexual heat control and control of associated aggressive behavior	Below 5 kg	1 drop	twice per day with an interval of 12 hours during 5-7 days	Not later than 2 days from the onset of sexual heat	<ol style="list-style-type: none"> <li>1. The drug is ineffective if more than 2 days have passed since the onset of sexual heat.</li> <li>2. Young male dogs receive a double single dose one time on the first day of the course.</li> <li>3. The pet becomes calm after a full course of use.</li> <li>4. In some cases, the use of the drug is extended until the termination of sexual heat.</li> <li>5. The course is repeated if necessary.</li> </ol>
		5,1 – 10 kg	2-4 drops			
		10.1-30 kg	5-8 drops			
		More than 30 kg	9 + 1 drop for each subsequent 5 kg of body weight			

It is not recommended to use the drug in young female dogs in first estrus as it is difficult to determine the time of the onset of sexual heat.

The reproductive function of the body is fully restored 2 to 3 months after withdrawal of the drug.

14. No symptom of an overdose of the drug is observed.

15. No specific features of the action of SEX BARRIER® drops for dogs during the first use or during withdrawal have been observed.

16. Do not use SEX BARRIER® drops for dogs in pregnant, lactating females, or in youngsters before age of puberty.

17. Do not skip the next dose of the drug, as this can lead to a decrease in therapeutic efficacy. If the established time for repeated use of the drug is missed, the drug should be used as soon as possible, in the same dosage and according to the same regimen.

If taking the drug is delayed for less than 12 hours, therapeutic efficacy does not decrease.

18. No side effects or complications following the use of SEX BARRIER® drops for dogs in accordance with these instructions are observed.

In the event of individual intolerance to the components of the drug, discontinue its use.

19. There is no information on the specific features of interaction with other drugs.

20. Do not use SEX BARRIER® drops for dogs in productive animals.

#### IV. Personal Safety

21. When using SEX BARRIER® drops for dogs, observe the general rules of personal hygiene and safety precautions provided for work with medicines.

22. After work, wash your hands with warm water and soap. People with hypersensitivity to the drug components should avoid direct contact with SEX BARRIER® drops for dogs. Never use empty package of the drug for domestic purposes; it must be disposed of with household waste.

23. In case of accidental contact of the drug with the skin or mucous membranes of the eyes, wash them with plenty of running water. In case of allergic reactions or if accidentally swallowed the drug, immediately seek medical advice (show the instructions for use of the drug or label to the physician).

Names and addresses of the production sites of the veterinary drug manufacturers.

1. Innovative Enterprise Astrapharm, LLC; 20, bldg 3, Nauchny proezd, Moscow, 117246. Tel./fax: (495) 785-

83-50/70.

2. RESEARCH AND PRODUCTION  
COMPANY "SKIFF", LLC; 20, bldg 3,  
Nauchny proezd, Moscow, 117246.

Name, address of the organization  
authorized by the holder or owner of the  
marketing authorization to accept  
consumer complaints.

Innovative Enterprise Astrapharm, LLC;  
20, bldg 3, Nauchny proezd, Moscow,  
117246.

Upon the approval of this prescribing information, the package insert for SEX  
BARRIER® drops for female and male dogs approved by Rosselkhoznadzor on  
March 16, 2016 shall no longer be in force.

Registration Certificate No.: 77-3-3.0-3660N<sub>o</sub>PVR-3-1.5/01394