by Rosselkhoznadzor on 10 April 2017

## INSTRUCTION for use of the veterinary drug SEX BARRIER® drops

for sexual heat control in female and male cats

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

### I. General Information

1. Trade name: SEX BARRIER® drops (SEX BARIER® guttae).

Generic name: meprenol acetate and ethinyl estradiol.

2. Pharmaceutical form: oral drops.

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

"for female cats": water-soluble mepregenol acetate - 1.00 mg and ethinyl estradiol - 0.01 mg;

"for male cats": water-soluble mepregenol acetate -4.00 mg and ethinyl estradiol -0.2 mg.

SEX BARRIER® drops contain the following 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 after the expiration date.

- 4. SEX BARRIER® drops are available in polyethylene vials with dispenser tips containing 2 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 with 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 out of the reach of children.
  - 7. Any unused drug is disposed of in accordance with the laws requirements.
  - 8. Prescription status: over-the counter product.

# II. Pharmacological Properties

- 9. Pharmacotherapeutic group: hormones and their antagonists.
- 10. SEX BARRIER® drops are a bi-hormonal contraceptive drug containing hormones as active substances: gestagen water-soluble mepregenol acetate and estrogen ethinyl estradiol.

Water-soluble meprenol acetate and ethinyl estradiol, acting on the hypothalamicpituitary 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 mepregenol 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 cats, 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 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 bi-hormonal contraceptive drug is intended for female cats for sexual heat control (interruption and delay of estrus), and for preventing unwanted pregnancy; for male cats for sexual heat control and control of associated aggressive behavior, urinary marking.
- 12. The contraindications of the drug include pregnant and lactating female cats, prepubescent animals, neoplasms of the mammary gland, diseases of the genital organs, diabetes mellitus, kidney stone disease and individual intolerance to the components of the drug.
- 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 cats	Sexual control	heat	Interruption of estrus	Below 5 kg	4 drops once per day			1. The drug is ineffective if more than 2 days have passed since the onset of estrus.
				More than 5 kg	5-7 drops once per day	3-5 days	No later than 2 days from the onset of estrus	<ol> <li>The pet becomes calm after a full course of use.</li> <li>In some cases, the use of the drug is extended until the termination of sexual heat.</li> <li>The course is repeated if necessary.</li> </ol>
			Estrus delay, maintaining of the calming effect	Regardless of the body weight of the pet	4 drops once per day	Regularly 1 time in 14 days	During anestrus or 10 days after the disappearance of signs of sexual heat	It can be carried out regularly without interruptions.
	Prevention pregnancy	of	unwanted	Regardless of the body weight of the pet	8 drops once per day	once	No later than 24 hours after mating	A later administration of the drug significantly reduces the effect of treatment.
Male cats	Sexual control control	heat and of	Interruption of sexual heat	Below 5 kg	4 drops once per day	4-6 days	No later than 2 days from the onset of sexual heat	1. The drug is ineffective if more than 2 days have passed since the onset of sexual heat.
	associated aggressive behavior, ur	inarv		More than 5 kg	5-7 drops once per			2. For young cats the drug is prescribed in a dose of 6-8 drops on the first day of the course, then

marking						according to the drug regimen. 3. In some cases, the use of the drug is extended until the termination of sexual heat. 4. The course is repeated if necessary.
	Maintaining the calming effect	Regardless of the body weight of the pet	4 drops once per day	Regularly 1 time in 14 days	During sexual rest	It can be carried out regularly without interruptions.

It is not recommended to use the drug in young females 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 during the first use or during withdrawal have been observed.
- 16. Do not use SEX BARRIER® drops 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 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 in productive animals.

### IV. Personal Safety

- 21. When using SEX BARRIER® drops, 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. 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 cats approved by Rosselkhoznadzor on March 16, 2016 shall no longer be in force.

Registration Certificate No.: 77-3-29.13-3659№PVR-3-0.3/01205