

INSTRUCTION
for use of the veterinary drug
SEX BARRIER® tablets for female cats and dogs
for sexual heat control in female cats and dogs

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

I. General Information

1. Trade name of the drug: SEX BARRIER® tablets for female cats and dogs (SEX BARRIER® tabulettae pro felis et canis feminae).

Generic name: meprenol acetate and ethinyl estradiol.

2. Pharmaceutical form: oral tablets.

The bi-hormonal contraceptive drug SEX BARRIER® tablets for female cats and dogs contains as active substances in one 100 mg tablet: water-soluble mepregenol acetate – 0.100 mg, ethinyl estradiol – 0.001 mg.

SEX BARRIER® tablets for female cats and dogs contain as excipients: lactose, calcium stearate, food colorant.

3. The drug is an oval, two-color tablet: white or white with a grayish tint on one side and light pink to dark pink with the logo “CB” on the other side.

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

Do not use SEX BARRIER® tablets for female cats and dogs after the expiration date.

4. SEX BARRIER® tablets for female cats and dogs are packed in blisters containing 10 tablets each. The blister with the drug is packaged in a cardboard box 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® tablets for female cats and dogs 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. Gestagen (mepregenol acetate) and estrogen (ethinyl estradiol) in the drug,

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 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.

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® tablets for female cats and 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. The bi-hormonal contraceptive drug SEX BARRIER® tablets for female cats and dogs are used for female cats and dogs for sexual heat control (interruption and delay of estrus), and preventing unwanted pregnancy.

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

It is not recommended to give the drug intended for male cats and dogs to female cats and dogs due to the different hormonal profile in females and males.

13. The drug is administered orally with feed or forcefully on the base of the tongue. The dosage depends on the body weight of the pet and the purpose of use (see Table 1).

Table 1

Pet type	Purpose of the drug		Pet weight, kg	Dosage	Course of use	Start of intake / notes
Female cats	Sexual heat control	Interruption of estrus	Below 5 kg	1 tablet	once per day during 3-5 days	1. Not later than 2 days from the onset of estrus. 2. The course is repeated if necessary.
			5.1 - 10 kg	1-2 tablets		
		Estrus delay, maintaining of the calming effect	Regardless of the body weight of the pet	1 tablet	Regularly 1 time in 14 days	1. During anestrus or 10 days after the disappearance of signs of sexual heat. 2. It can be carried out regularly without interruptions.
	Prevention of unwanted pregnancy after accidental mating		Regardless of the body weight of the pet	2 tablets	one time	Not later than 24 hours after accidental mating
Female dogs	Sexual heat control	Interruption of estrus	below 5 kg	1 tablet	once per day during 3-5 days	1. Not later than 2 days from the onset of estrus. 2. It is recommended that
			5.1-10 kg	1-2 tablets		

			10.1-30 kg	2-4 tablets		estrus should be interrupted no more than 1 time per year.
		Delay of estrus	more than 30 kg	4 + 1 tablet for each subsequent 10 kg of body weight	once per day during 5-7 days	1. 7-14 days before supposed estrus. 2. Makes it possible to delay estrus for about 20-40 days. 3. It is recommended that estrus should be delayed no more than 2 time per year.
	Prevention of unwanted pregnancy after accidental mating					once per day during 2 days

It is not recommended to use the drug in young female pets 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® tablets for female cats and dogs during the first use or during withdrawal have been observed.

16. Do not use SEX BARRIER® tablets for female cats and 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® tablets for female cats and 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® tablets for female cats and dogs in productive animals.

IV. Personal Safety

21. When using SEX BARRIER® tablets for female cats and 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® tablets for female cats and 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. Innovative Enterprise Astrapharm, LLC; 20, bldg 3, Nauchny proezd, Moscow, 117246. Tel/fax: (495) 785-83-50/70.

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® tablets for female cats and dogs approved by Rosselkhoznadzor on 15 November 2011 shall no longer be in force.

Registration Certificate No.: 77-3-2.17-3582№PVR-3-1.0/00311