

INSTRUCTION
for use of the veterinary drug
SEX BARRIER® tablets for male cats and dogs
for sexual heat control in male 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 male cats and dogs (SEX BARRIER® tabulettae pro felis et canis masculum).

Generic name: meprenol acetate and ethinyl estradiol.

2. Pharmaceutical form: oral tablets.

The bi-hormonal contraceptive drug SEX BARRIER® tablets for male cats and dogs contains as active substances in one 100 mg tablet: water-soluble mepregenol acetate – 0.40 mg, ethinyl estradiol – 0.02 mg.

SEX BARRIER® tablets for male cats and dogs contain the following 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 blue to dark blue 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 male cats and dogs after the expiration date.

4. SEX BARRIER® tablets for male cats and dogs are available 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 male 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. The hormones used in the drug are: gestagen – mepregenol acetate and

estrogen – ethinyl estradiol, acting on the hypothalamic-pituitary system of animals, reduce the secretion of gonadotropic hormones (FSH and LH) from the hypophysis. Due to this, in male cats and 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® tablets for male 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 male cats and dogs is used:

- in male cats to control sexual heat and associated aggressive behavior, urinary marking and maintaining calming effects;
- in male dogs to control sexual heat and associated aggressive behavior.

12. The contraindications of the drug include Greyhounds, prepubescent animals, 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 female cats and dogs to male cats and dogs due to the different hormonal profile in males and females.

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
Male cats	Sexual heat control and control of associated aggressive behavior, urinary marking	Below 5 kg	1 tablet	once per day during 3-5 days	No later than 2 days from the onset of sexual heat
		5.1 - 10 kg	1-2 tablets		
	Maintaining of the calming effect	Regardless of the body weight of the pet	1 tablet	Regularly 1 time in 14 days	During sexual rest
Male dogs	Sexual heat control and control of associated aggressive behavior	below 5 kg	1 tablet	once per day during 3-5 days	No later than 2 days from the onset of sexual heat
		5.1-10 kg	1-2 tablets		
		10.1-30 kg	2-4 tablets		
		more than 30 kg	4 + 1 tablet for each subsequent 10 kg of body weight		

The reproductive function of the pets 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 male cats and dogs during the first use or during withdrawal have been observed.

16. Never use SEX BARRIER® tablets for male cats and dogs under 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 male 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 male cats and dogs in productive animals.

IV. Personal Safety

21. When using SEX BARRIER® tablets for male 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 male 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 male cats and dogs approved by Rosselkhoznadzor on 15 November 2011 shall no longer be in force.