

®
CIPROVET
5%

for injection

PACKAGE LEAFLET

for veterinary use of the drug product CIPROVET® 5% for injection

Approved by: N. A. Vlasov, the Deputy Head of the Federal Service for Veterinary and
Phytosanitary Surveillance

(Development organization: NVTs Agrovetzashchita Ltd., bld. 2, 4, Igarskii passage, Moscow,
129329 Russia)

Marketing Authorisation No.: in Russia 77-3-7.15-4035 No. IIBP-3-4.0/02560 dated 20.02.2018

I. General notice

The name of the drug product for veterinary use:

Trade name – CIPROVET® 5% for injection; International nonproprietary name: ciprofloxacin.

Dosage form: solution for injections.

The drug product contains the following active ingredient in 1 ml of the solution: ciprofloxacin – 50 mg and the excipients like amber acid, trilon B and water for injections. Appearance: the drug product represents a transparent solution of light yellow color.

The shelf life of the drug product shall be 2 years from the manufacturing date at compliance with the recommended storage conditions in the tightly closed packaging provided by the manufacturer, and 21 days after the first opening of the vial. Taking of the drug product after the expiration date is prohibited.

CIPROVET® 5% for injection is packaged in the 10, 20, 50, 100 and 200 ml dark glass vials of correspondent capacity sealed with rubber stoppers and aluminum caps. The vials of 10, 20, 50 ml are individually packed into cardboard boxes. Every consumer package contains the package leaflet for use of the drug product.

The drug product is stored tightly closed in the packaging provided by the manufacturer, in the place protected from direct sunlight, separately from foodstuff and fodders, at the temperatures from 0°C to 25°C.

CIPROVET® 5% for injection must be kept out of reach of children.

Unused drug product should be disposed in accordance with legal requirements.

Available without a veterinarian's prescription.

II. Pharmacological properties

CIPROVET® 5% for injection belongs to antibacterial drug products of the group of fluoroquinolones.

Ciprofloxacin included into the composition of the drug product possesses a broad range of antibacterial action; it is active against most gram-positive and gram-negative microorganisms, including *Escherichia coli*, *Salmonella spp.*, *Enterobacter spp.*, *Proteus mirabilis*, *Proteus vulgaris*, *Haemophilus spp.*, *Klebsiella*, *Pasteurella multocida*, *Corynebacterium*, *Pseudomonas aeruginosa*, *Bordetella*, *Campylobacter*, *Erysipelothrix*, *Staphylococcus spp.*, *Streptococcus spp.*, *Actinobacillus spp.*, *Clostridium spp.*, *Fusobacterium spp.*, *Bacteroides spp.*, *Brucella spp.*, *Chlamydia spp.*, as well as *Mycoplasma spp.*

The mechanism of bactericide action of ciprofloxacin is in blocking the bacterial DNA-gyrase that results in breaching of the bacteria division due to suppression of the DNA synthesis, as well as in developing of morphologic changes of the cell wall and the bacterial cell membranes.

After parenteral administration of the drug product, ciprofloxacin is easily absorbed in the blood from the injection site and penetrates to most parts of the body and tissues (except for the tissues, which are rich in lipids), it penetrates into the pleura, abdomen, eye fluid and placenta. Maximum concentration of ciprofloxacin in blood serum of the animals is observed after 0.5 to 1 hour, therapeutic concentration is maintained during 24 hours. Ciprofloxacin

is excreted from the body primarily in an unchanged form and partially in the form of metabolites with urine and gall, as well as with milk in lactating animals.

In terms of the effect upon the animal body the drug product CIPROVET® 5% for injection can be referred to moderately hazardous substances (hazard class 3 according to GOST 12.1.007-76). Under the condition of compliance with the recommended dosage it is well tolerated by the animals and possesses no embryotoxic or teratogenic effects.

III. Indications

CIPROVET® 5% for injection is administered to bovine, sheep, goats, porcine, dogs and cats at the diseases of bacterial etiology of gastrointestinal tract, respiratory system, urogenital system, joints, soft tissues and skin, including necrobacteriosis, bronchopneumonia, colibacteriosis, salmonellosis, pastereullosis, mycoplasmosis, umbilical infection, metritis, mastitis and agalactia (MMA) syndrome and other primary and secondary infections, the pathogens of which are sensitive to ciprofloxacin.

Contraindications for taking of the drug product CIPROVET® 5% for injection include increased individual sensitivity of the animal to the ingredients of the drug product (including cases in the past history) and expressed dysfunctions of kidneys and liver. The drug product must not be administered at substantial defects of development of the cartilaginous tissue, affections of nervous system accompanied by convulsions; as well as to puppies and kittens during the first year of life until completion of the period of growth. It is prohibited to give the drug product to dairy female animals, the milk of which is used for alimentary purposes.

The requirements set to personal hygiene and labor safety and health regulations imposed on handling drug products must be complied with while handling CIPROVET® 5% for injection. At incidental contact of the drug product with skin or eye mucosa rinse thoroughly with plenty of water. People with hypersensitivity to the ingredients of the drug product must avoid direct contacting with the drug product CIPROVET® 5% for injection. In the event of occurrence of allergic reactions or at incidental swallowing of the drug product consult the physician immediately (take away with you this package leaflet or the drug product label).

Administration of the drug product CIPROVET® 5% for injection to pregnant and lactating female animals and to the puppies and kittens under 1 year of age is not allowed.

CIPROVET® 5% for injection is administered to bovine, sheep and goats subcutaneously or intramuscularly; to porcine intramuscularly in the dosage 1 ml per 10 kg of animal body weight (5 mg of ciprofloxacin per 1 kg of animal body weight), once daily during 3 to 5 days; porcine with the MMA syndrome – during 2 days; dogs and cats – subcutaneously during 5 to 10 days. Maximum amount of the drug product CIPROVET® 5% for injection used for administration in one injection site must not exceed for bovine – 15 ml, porcine – 10 ml, sheep and calves – 5 ml, pigs – 2.5 ml, dogs – 2 ml and cats – 1 ml.

At taking of CIPROVET® 5% for injection in accordance

with this package leaflet no side effects and complications are observed, as a rule. In the cases of increased individual sensitivity of the animal to the ingredients of the drug product and occurrence of side effects (refusal of fodder, vomiting, edemas, loss of coordination (ataxia) and balance) taking of the drug product is terminated and desensibilizing and symptomatic therapy should be administered.

Loss of appetite, depressed state and vomiting can be observed in the animal at overdosing of the drug product.

Taking of the drug product CIPROVET® 5% for injection is not allowed simultaneously with bacteriostatic antibiotics (levomycetin, macrolides and tetracyclines), theophylline, and non-steroid anti-inflammatory drug products.

No particularities of action of the drug product at its first use

and termination of use are revealed.

Non-compliance with the recommended scheme for proper use of the drug product must be avoided because it might result in decreasing of the therapeutic efficiency. At missing of one dosage taking of the drug product must be renewed as soon as possible in the prescribed dosage and under the same treatment schedule.

Slaughter of bovine, sheep and goats for meat is allowed not earlier than in 28 days and porcine – not earlier than in 14 days after the last taking of CIPROVET® 5% for injection. Meat of the animals brought to an involuntary slaughter before expiration of the abovementioned term may be used for feeding of fur-bearing animals.

/AVZ
animal
health/

Name and address of the production site of the manufacturer of the drug product for veterinary use:

AVZ S-P LTD., 1, Tsentralnaia str., Sergiyev Posad, Moscow region , 141305 Russia.

Name and address of the organization authorized by the marketing authorization holder or owner of the drug product to accept claims from the consumers: AVZ S-P LTD., 1, Tsentralnaia str., Sergiyev Posad, Moscow region , 141305 Russia.

24-hour hotline: 8-800-700-19-93 (toll free in Russia).

See information on product conformity assessment at: www.vetmag.ru.