

LEAFLET FOR:**GENTAMICIN 40 mg/mL solution for injection
GENTAMICIN 40 mg/mL solutio pro injectionibus**

For calves, swine, dogs and cats, Guinea pigs, mice, ornamental birds (parrots, pigeons and others)

1. NAME AND ADDRESS OF THE AUTHORIZATION HOLDER AND OF THE PRODUCER (IF THEY DIFFERENT)

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2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GENTAMICIN 40 mg/mL solution for injection

GENTAMICIN 40 mg/mL solutio pro injectionibus

3. ACTIVE SUBSTANCE AND EXCIPIENTS

1.0 mL of the preparation contains:

Active Substance:

40 000 IU Gentamicin sulphate

Excipients:

Methyl Parahydroxybenzoate, Propyl Parahydroxybenzoate, Anhydrous Sodium Sulphite, Disodium Edetate, Water for injection.

4. THERAPEUTIC INDICATIONS

For the treatment of respiratory, gastro-intestinal and genito-urinary infections, infected wounds, arthritis, polyarthritis, bacterial superinfections in virus diseases, MMA-syndrome (methylmalonic acidemia) in swine, otitis, tonsillitis, ophthalmitis, pyoderma, infections caused by staphylococcus, contagious cold and mycoplasma.

5. CONTRAINDICATIONS

Not to be used in severe renal failure; during pregnancy; in animals with vestibular and disorders and otologic problems.

6. ADVERSE REACTIONS

Nephro- and ototoxicity are characteristic and common when aminoglycoside antibiotics are administered. Pain and inflammation at the site of injection as well as hypersensitivity reactions can also be observed.

If you notice any serious impact or other effects due to the administration of this VMP, not listed in the leaflet, please, inform your veterinarian.

7. ANIMAL SPECIES, FOR WHICH THIS VMP IS DESIGNED

For calves, swine, dogs and cats, Guinea pigs, mice, ornamental birds (parrots, pigeons and others)

8. RECOMMENDED DOSES FOR EACH OF THE ANIMAL SPECIES, ADMINISTRATION ROUTE

Routes of administration: intramuscularly, subcutaneous and in extremely severe cases – by slow intravenous infusion.

Dose:

Calves and swine – 3 to 4 mg/kg b.w. (0.8 to 1 mL for 10 kg b.w.) every 12 hours the first day followed by once daily; през 12 часа първия ден и след това един път дневно;

Dogs and cats – 4 to 8 mg/kg b.w. (1 to 2 mL for 10 kg b.w.) twice daily the first day followed by once daily;

Guinea pigs, mice – 5 mg/kg b.w. (0.125 mL/kg b.w.) every 24 hours;

Ornamental birds (parrots, pigeons and others) – 5 mg/kg b.w. for the larger animals and 10 mg/kg b.w. for the smaller animals intramuscularly 2 to 3 times daily.

In newborn animals and in the first 3 days after birth half of the respective dose is administered following the same scheme. The treatment lasts 3 to 5 days.

9. ADVICE FOR PROPER ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Calves:

Meat and internal organs: 90 days.

Swine:

Meat and internal organs: 40 days.

11. SPECIAL CONDITIONS FOR STORAGE OF THE VMP

Keep the medication out of sight and reach of children!

Do not store above 25°C.

Protect from light.

Keep in dry place.

Following withdrawal of the first dose, use the product within 28 days.

To be stored in a refrigerator at 2 °C – 8 °C.

12. SPECIAL PRECAUTIONS FOR USE

Pregnancy and lactation:

Not to be used during pregnancy and breast feeding.

Interactions with other veterinary medicinal products and other forms of interactions:

Do not administer with furosemide, heparin, general anesthetics, muscle relaxants, as well as with other aminoglycoside antibiotics (danger of amplification of the neurotoxic and nephrotoxic effects). In solution *in vitro* shows incompatibility with β -lactam antibiotics (penicillins and cephalosporins), water soluble sulfonamides, erythromycins and vitamins of the B vitamin complex.

Overdose:

If this VMP is administered in high doses for a long period of time it could injure the function of the auditory and vestibular system and the kidneys. It could also block the neuromuscular conductivity.

Hemodialysis and peritoneal dialysis are recommended.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM THE USE OF SUCH PRODUCTS

The VMP should not be disposed of together with household wastes or sewage. Ask your veterinarian what to do with the no longer necessary VMPs. These measures would help environmental protection.

14. DATE OF THE LAST UPDATE OF THE TEXT

31/03/2014

15. ADDITIONAL INFORMATION

Not all the sizes of the package can be on the market.

Please, contact the local representative of the authorization holder for any information concerning this veterinary medicinal product.