

LEAFLET

NIGER[®] injectable solution
FOR ANIMAL TREATMENT ONLY

1. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER AND OF THE MANUFACTURING AUTHORIZATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorization holder:

PROVET S.A.

77, Posidonos Avenue

174 55 Alimos, Attiki

Tel.: +30 2105575770-3

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E-mail: vet@provet.gr

2. NAME OF THE VETERINARY MEDICINAL PRODUCT
NIGER[®] injectable solution

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

1 ml of solution contains:

Active substance: 250 mg Kanamycin (as sulfate)

Excipients: Methylparaben, Propylparaben, Sodium metabisulfite, Sodium citrate 2H₂O, Water for injections

4. INDICATION(S)

Kanamycin is indicated for the treatment of localized and generalized infections caused by susceptible Gram positive and negative aerobic bacteria. Specifically, NIGER injectable solution is recommended in the following cases:

- Localized and generalized staphylococcal infections, septicemia, colibacillosis, salmonellosis, osteomyelitis, peritonitis, otitis externa and media
- Infections of the urinary and genital system, such as cystitis, metritis
- Infections of the respiratory system, such as nasal sinusitis, laryngitis, tracheitis, tracheobronchitis and bronchopneumonia
- Secondary bacterial infections
- Post-operative treatment

5. CONTRAINDICATIONS

As with all aminoglycosides, kanamycin should not be administered to:

- a) animals sensitive to kanamycin
- b) animals with renal impairment
- c) animals with neuromuscular disorders
- d) newborn animals
- e) during pregnancy

6. ADVERSE REACTIONS

In addition to hypersensitivity reactions and neuromuscular blockade, aminoglycosides also generally exhibit ototoxicity and nephrotoxicity.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep, Goats, Dog, Cat

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

It is administered intramuscularly.

Sheep-Goats: 12 mg kanamycin/ kg of b.w. or 2 ml NIGER injectable solution/ 40 kg of b.w. every 12 hours

Dog-Cat: 8 mg kanamycin/ kg of b.w. every 12 hours
Treatment is administered for up to 3 days.

9. ADVICE ON CORRECT ADMINISTRATION

It is recommended to carefully monitor the renal function of the animal and allow abundance of water consumption during treatment.

It should be used with caution in cats, because they are particularly sensitive to toxic effects on the inner ear.

Use NIGER injectable solution with caution to dogs.

10. WITHDRAWAL PERIOD

Sheep: Meat and edible tissues: 78 days

Goats: Meat and edible tissues: 117 days

Sheep-Goats: Milk: 3 days

11. SPECIAL STORAGE PRECAUTIONS

Store at temperatures below 25 °C.

Shelf life of the veterinary pharmaceutical product after first opening of the container: 28 days

12. SPECIAL WARNING(S)

Attention to concurrent administration of aminoglycosides with other nephrotoxic medicines, muscle relaxants, as well as with inhalant anesthetic gases (eg halothane). Also, the ototoxicity of aminoglycosides is enhanced by loop diuretics (eg furosemide).

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. OTHER INFORMATION

PACKAGES

Vials of 4 ml, 20 ml, 40 ml and 100 ml

Not all pack sizes may be marketed.

Marketing Authorization Number: 85082/02-12-2011/K-0046901

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorization holder.

under veterinary medical prescription
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN