PACKAGE LEAFLET

For animal treatment only

NIGER

Injectable solution of kanamycin for sheep, goats, dogs, cats

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

Marketing Authorisation Holder:
PROVET S.A.
120, Eleftherias Avenue, Eleousa, Zitsa, 45500 Ioannina, Greece
Tel.: +30 2105508500, +30 2105575770-3
E-mail: vet@provet.gr

Manufacturer responsible for batch release:
PROVET S.A. (FACTORY)
Nikiforou Foka & Ag.Anargyron, Thesi Vrago,
193 00 Aspropyrgos, Attiki, Greece

2.NAME OF THE VETERINARY MEDICINAL PRODUCT

NIGER
Injectable solution
Kanamycin
250 mg/ml
Sheep, Goats, Dog, Cat

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. INDICATIONS

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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES
Sheep, Goats, Dog, Cat

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION
It is administered intramuscularly.
Sheep-Goats: 12mg kanamycin/kg of b.w. or 2ml NIGER injectable solution/ 40kg of b.w. every 12 hours
Dog-Cat: 8mg 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 offal's: 78 days
Goats: Meat and offal's: 117 days
Sheep-Goats: Milk: 3 days

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
Store at temperatures below 25 °C.
Shelf life of the veterinary pharmaceutical product after first opening of the container: 28 days
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS
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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED
DECEMBER 2011

15. OTHER INFORMATION
PACKAGES
Vials of 4 ml, 20 ml, 40 ml and 100 ml
Not all pack sizes may be marketed.

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 SIGHT AND REACH OF CHILDREN