LEAFLET

GENTAMICIN/ PROVET injectable solution 5%

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
+30 210 5508500
Fax: +30 2105575830
E-mail: vet@provet.gr

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GENTAMICIN/ PROVET injectable solution 5%

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

1 ml of solution contains:
Active substance: 50 mg Gentamicin base (as sulfate)
Excipients: Sodium metabisulfite, Disodium edetate, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Water for injection

4. INDICATION(S)

It is generally recommended for the treatment of infections of the gastrointestinal tract, urinary, genital and respiratory systems. It is effective in treating infections of dogs and cats, such as metritis, cystitis, nephritis, pneumonia, bronchitis and otitis, as well as for infections, such as colibacillosis, bronchitis, pneumonia and generally gastrointestinal infections of calves.
It is indicated for infections due to Gram negative as well as Gram positive bacteria and mycobacterium. It is specifically recommended for infections due to aerobic Gram negative bacteria, such as *Escherichia coli*, *Klebsiella* spp., *Proteus* spp., *Enterobacter* and *Pseudomonas* spp.

5. CONTRAINDICATIONS

Gentamicin should be avoided in animals with known hypersensitivity to aminoglycosides, during pregnancy (penetrates the placenta and causes embryo ear and kidney damage), in cases of renal insufficiency and neuromuscular disorders. It should also be avoided in young or senior animals. Do not administer to rabbits. Do not administer to milk producing animals.

6. ADVERSE REACTIONS

Gentamicin may cause hypersensitivity reactions, kidney damage, hearing impairment or even deafness, neuromuscular depression, low blood pressure, bradycardia, oedema and pain at the injection site, nausea, increase of transaminase enzymes and alkaline phosphatase.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Calves, Dog, Cat

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
It is administered intramuscularly.
Calves: the recommended dose is 2 mg gentamicin/ k.g. of b.w. equivalent to 2 ml GENTAMICIN injectable solution 5% per 50 kg of b.w. every 8 hours for the first day and every 24 hours for the next two days.
Dog-Cat: the recommended dose is 4.5 mg gentamicin/ k.g. of b.w. equivalent to 0.45 ml GENTAMICIN injectable solution 5% per 5 kg of b.w. every 12 hours for the first day and every 24 hours for a period of 5-7 days under veterinary supervision.
If no clinical improvement is achieved within 2-3 days, it is recommended to revise the diagnostic and therapeutic approach.

9. ADVICE ON CORRECT ADMINISTRATION
None

10. WITHDRAWAL PERIOD
Calves: Meat and offal: 80 days
Dog-Cat: Not applicable.

11. SPECIAL STORAGE PRECAUTIONS
Store in a cool and dry place protected from light at temperatures below 25 °C.
Shelf life after first opening of the immediate packaging: 28 days

12. SPECIAL WARNING(S)
Do not administer gentamicin concurrently with other nephrotoxic or neurotoxic substances (other aminoglycosides, amphotericin B, vacitracin, cisplatin, methoxyfluorane, polymixin B, vancomicin, furosemide, mannitol) due to increased nephrotoxicity and neurotoxic action. The concurrent administration of gentamicin with general anesthetics or substances causing neuromuscular suppression, should be avoided due to increased neuromuscular suppression.

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 50 ml and 100 ml
Not all pack sizes may be marketed.

Marketing Authorization Number: 85081/02-12-2011/K-0041202

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