PACKAGE LEAFLET

For animal treatment only

GENTAMICIN/ PROVET 5%

Injectable solution of gentamycin for calves, dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION 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

GENTAMICIN/ PROVET
injectable solution
Gentamicin 50 mg/ml
for calves, dogs, cats

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

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

4. INDICATIONS

GENTAMICIN /PROVET injectable solution 5% 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.

GENTAMICIN/PROVET injectable solution 5% 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, acoustic impairment or deafness, neuromuscular depression, low blood pressure, bradycardia, oedema and pain at the injection site, nausea, increase of transaminase enzymes and alkaline phosphatase.

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
Calves, Dog, Cat

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Administer intramuscularly.
Calves: the recommended dose is 2mg gentamicin/ kg of b.w. that is equivalent to 2ml **GENTAMICIN /PROVET injectable solution 5%** / 50kg b.w. every 8 hours the first day and then every 24 hours for the next 2 days.
The repeated injections should take place in different injection sites every time.
Dogs, Cats: the recommended dose is 4.5mg gentamicin/ kg b.w. that is equivalent to 0.45ml **GENTAMICIN PROVET injectable solution 5%** / 5kg b.w. every 12 hours the first day and then every 24 hours for a period of 5-7 days, under veterinary supervision.
In case that no clinical improvement is seen within 2-3 days, repetition of sensitivity testing and therapy is recommended.

9. ADVICE ON CORRECT ADMINISTRATION
None

10. WITHDRAWAL PERIOD
Due to the accumulation of gentamicin at the liver, kidneys and injection site, any repeated therapy cycle during the withdrawal period should be avoided.
Calves: Intramuscular use: Meat & offal: 192 days.

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
Store below 25°C. Store in a cool, dry place protected from light.
Shelf-life after first opening the immediate packaging: 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
Gentamicin should not be administered concurrently with other nephrotoxic or neurotoxic substances (other aminoglycosides, amphotericin B, bacitracin, cisplatin, methoxyflurane, polymyxin B, vancomycin, furosemide, mannitol) as in this case there is an increase in their nephrotoxic or neurotoxic action. Moreover, the concurrent administration of gentamicin with general anesthetics or substances causing neuromuscular suppression should be avoided, as it enhances their 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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED
DECEMBER 2019

15. OTHER INFORMATION
PACKAGES
Vial of 50 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 THE SIGHT AND REACH OF CHILDREN