The following text is currently approved by the National Organization for Medicines (E.O.F.) in Greece and is subject to changes at any time.

PACKAGE LEAFLET

For animal treatment only

DIHYDROSTREPTOMYCIN/ PROVET

injectable solution for lambs and dogs

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

DIHYDROSTREPTOMYCIN/PROVET
injectable solution
Dihydrostreptomycin 250 mg/ml
for lambs, dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml of solution contains:
Active substance: Dihydrostreptomycin base (as dihydrostreptomycin sulfate) 250 mg
Excipients: Sodium citrate dihydrate, Sodium formaldehyde sulfoxylate, Methyl parahydroxybenzoate, Water for injections

4. INDICATIONS

Indicated for the treatment of infections caused by microorganisms susceptible to dihydrostreptomycin.
Lambs: pasteurellosis, enteritis, respiratory infections, staphylococcal and streptococcal infections
Dog: pasteurellosis, leptospirosis, enteritis, endometritis, respiratory infections, postpartum infections, staphylococcal and streptococcal infections

5. CONTRAINDICATIONS

Dihydrostreptomycin is not indicated for infections caused by dihydrostreptomycin-resistant microorganisms.
Do not administer to animals with known hypersensitivity to dihydrostreptomycin.
Do not administer intravenously, for shock may occur.
Do not administer to animals with renal insufficiency.

6.ADVERSE REACTIONS

In the rare cases of hypersensitivity reactions, treatment should be discontinued. Dihydrostreptomycin is ototoxic and nephrotoxic.

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
Lambs, Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Administer intramuscularly. Use different injection sites for several administrations.
The dosage varies from 5-30 mg/ kg of b.w. depending on the age and the animal species. The usual dose is 10 mg/ kg of b.w.
Lambs-Dog: 10 mg as dihydrostreptomycin/ kg of b.w.
In order to maintain the therapeutic blood levels of the drug, the doses mentioned must be repeated every 12 hours for 3-4 days depending on each specific case.

9. ADVICE ON CORRECT ADMINISTRATION
None

10. WITHDRAWAL PERIOD
Lambs: Meat & edible tissues: 40 days

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
Store below 25°C.
Shelf-life after the first opening of 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
Increased nephrotoxicity may occur, when dihydrostreptomycin is administered concurrently with other potentially nephrotoxic antibacterials. Neuromuscular blockade may take place upon concurrent administration of aminoglycosides and muscle relaxants. Increased ototoxicity when administered concurrently with diuretics, such as furosemide. It is observed greater cardiac muscle function suppression, when administered to animals during anesthesia with halothane. Aminoglycosides present synergistic action, when administered simultaneously with b-lactamase sensitive penicillins.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Due to the possibility of skin sensitization of persons handling dihydrostreptomycin, the use of appropriate protective gloves is recommended.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTEMATERIALS, 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
AUGUST 2010

15. OTHER INFORMATION
PACKAGE
Vial of 12 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