PACKAGE LEAFLET

For animal treatment only

NEO-AMPIVET injectable suspension

of penicillin & dihydrostreptomycin for sheep, goats, pigs, dog, cat

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 & Agion Anargyron, Thesi Vrago,
193 00 Aspropyrgos, Attiki, Greece

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEO-AMPIVET
injectable suspension
Benzylpenicillin procaine+ Dihydrostreptomycin base (200+250) mg/ml
for sheep, goats, pigs, dog, cat

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 ml of suspension contains:
Active substances:
Benzylpenicillin procaine 200.000 I.U. (equivalent to 200 mg Benzylpenicillin procaine)
Dihydrostreptomycin base 250 mg (as sulfate)

Excipients: Procaine hydrochloride , Sodium citrate dihydrate, Sodium formaldehyde sulfoxylate NF, Povidone K17 (Polyvinylpyrrolidone), Citric acid, Disodium edetate, Antifoam, Tween 80, Nipasept sodium, Cetrimide, Water for injections

4. INDICATIONS

NEO-AMPIVET injectable suspension is recommended for the treatment of mixed infections caused by microbes susceptible to the combination of penicillin-streptomycin. Specifically, the above combination is effective against: mastitis due to Gram positive and negative microorganisms, streptococcal, staphylococcal and colibacillic infections, endometritis and generally puerperal infections, as well as infections of the respiratory and urinary system and of the digestive tract.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity.
Do not use in animals with hepatic and renal insufficiency.
Do not administer intravenously, for anaphylactic shock may occur.

6. ADVERSE REACTIONS

Prolonged use of streptomycin in high doses can be ototoxic and nephrotoxic, especially in cats and dogs. Occasionally, transient allergic reactions can be observed due to penicillin and are treated with antihistamine products and epinephrine.

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, Pigs, Dog, Cat

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION
Administer intramuscularly.
Sheep-Goats-Pigs: 1 ml NEO-AMPIVET per 22 kg of body weight
Dog-Cat: up to 1 ml NEO-AMPIVET per 10 kg of body weight
Treatment should not exceed 5 days in total.

9. ADVICE ON CORRECT ADMINISTRATION
Shake well before use.

10. WITHDRAWAL PERIOD
Sheep-Goats: Meat & offal: 35 days
Milk: 48 hours
Pigs: Meat & offal: 32 days

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
Store below 25°C.
Shelf-life after first opening the immediate packaging: 20 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
Do not use during pregnancy.
Do not combine it with other antibacterial products containing sulfonamides and tetracyclines due to antagonistic mode of action.
In case of overdose, symptoms of nephrotoxicity and ototoxicity should be expected. Immediate discontinuation of treatment is recommended.
People with known hypersensitivity to penicillin or streptomycin should avoid contact with the veterinary medicinal product.

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
APRIL 2013

15. OTHER INFORMATION
PACKAGES
Vials of 20 ml, 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