PACKAGE LEAFLET

For animal treatment only

PANGOLAMIN

injectable suspension of Penicillin for horse, cattle, sheep, goat, pig, 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 & Ag.Anargyron, Thesi Vrago,
193 00 Aspropyrgos, Attiki, Greece

2.NAME OF THE VETERINARY MEDICINAL PRODUCT

PANGOLAMIN
injectable suspension
300.000 IU/ML
for horse, cattle, sheep, goat, pig, dog, cat

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 ml of suspension contains:
Active substance: 300.000 IU Benzylpenicillin Procaine

Excipients: Methyl Parahydroxybenzoate, Sodium Citrate, Lecithin, Povidone, Dissodium Edetate, Sodium Thiosulfate, Potassium Dihydrogen Phosphate, Water for injections.

4. INDICATIONS

PANGOLAMIN injectable suspension is indicated for the treatment of mastitis, particularly in cases of streptococcal and staphylococcal origin. Systemic and localized infections, pneumonia and bronchopneumonia, infections of the tonsils, pyelonephritis and *Actinomyces* spp. infections of the cattle, swine erysipelas, leptospirosis, abortions due to *Campylobacter foetus*, conjunctivitis and otitis.

5. CONTRAINDICATIONS

Do not administer to animals with a known hypersensitivity to the active ingredient or to any of the excipients.

6. ADVERSE REACTIONS

Occasionally, following frequent administrations of penicillin, allergic reactions may be observed, particularly to dogs, with symptoms such as pruritus, skin rash etc. These are treatable with the use of antihistamine products. During intramuscular injection in companion animals, transient and painful oedema may occur.
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
Horse, Cattle, Sheep, Goat, Pig, Dog, Cat

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
It is administered intramuscularly
Dose ranges from 5000-25000 I.U./ kg of b.w.
Horses-Cattle: 1-2.5 ml/ 50 kg of b.w.
Calves-Sheep-Goats-Pigs: 1-2 ml/ 25 kg of b.w.
Dog-Cat: 1 ml/ 12 kg of b.w.
The above-mentioned dose is administered intramuscularly every 24 h.
Higher doses are recommended to companion animals, as well as to productive animals in acute infections. The exact dose must be determined by the veterinarian.

9. ADVICE ON CORRECT ADMINISTRATION
Product must be shaken well before use.

10. WITHDRAWAL PERIODS
Meat and offal:
Cattle: 10 days
Sheep-Goats: 9 days
Pigs: 7 days
Milk (Cattle, Sheep, Goats): 3 days

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
Store below 25^{o}C.
Protected from light.
Store in a dry place.
Shelf life after 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/carton box. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS
Special warnings for each target species: None
Special precautions for use in animals: None
Special precautions to be taken by the person administering the veterinary medicinal product to animals: Due to hypersensitivity, allergic reactions may occur in people who frequently come in contact with the penicillin suspension.
Pregnancy and lactation: No restriction
Interaction with other medicinal products and other forms of interaction:
Do not combine with other antibacterial products containing sulfonamides, chloramphenicol or tetracyclines due to antagonistic mode of action. In contrast, it has a synergistic effect with aminoglycoside antibiotics, such as streptomycin, neomycin, kanamycin and gentamicin. It should not be combined or co-administered with solutions containing sodium bicarbonate or dextrose.
Overdose (symptoms, emergency procedures, antidotes): No data is available
Incompatibilities: None are known

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
MARCH 2022

15. OTHER INFORMATION

PACKAGE
Vial of 20ml 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