

PACKAGE LEAFLET

For animal treatment only

ZADAREP

oral solution of Vit A, Vit D3, Vit E, Vit C for Horses, Cattle, Pigs, Poultry and Rabbits

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

ZADAREP

oral solution

Vitamin A, Vitamin D3, Vitamin E, Vitamin C

(50,000 IU+5,000 IU+30mg+100mg)/ml,

for Horses, Cattle, Pigs, Poultry, Rabbits

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each ml of solution contains:

Active substances: 50.000 I.U. Vitamin A (as palmitate), 5.000 I.U. Vitamin D₃, 30 mg Vitamin E (as acetate), 100 mg Vitamin C (as sodium ascorbate)

Excipients: Butylated hydroxyanisole (BHA), Butylated hydroxytoluene (BHT), Ethoxyquin, Cremophor L, Glycerol, Disodium hydrogen phosphate, Citric acid, Potassium sorbate, Water

4. INDICATIONS

It is recommended for the treatment of primary or secondary cause vitamin A, D₃, E and C deficiencies. For the reinforcement of the organism in stress related situations (pregnancy, lactation, egg production). Reinforcement of the organism's immune system against infectious agents and enhancement of immune system after vaccinations.

Supportive to the animals in case of stress related to transport, weaning, groupings, sudden temperature fluctuations etc.

Especially in poultry, the addition of vitamin C aids birds to withstand high temperatures, to maintain high egg production levels and enhances resistance of the eggshell.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

None.

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

Horses, Cattle, Pigs, Poultry, Rabbits

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The following doses are generally administered as one single dose or for 2-5 consecutive days, according to the severity of the condition.

Per 100 chicks:

1 day old: 2 ml / ½ L of water

4 weeks old: 10 ml / 1 L of water

Per 100 chickens:

8 weeks old: 10 ml / 2 L of water

12 weeks old: 10 ml / 3 L of water

16 weeks old: 10 ml / 4 L of water

Per 100 laying hens or reproductive parents: 20 ml / 6 L of water

Per piglet: 1 ml

Per sow: 6 ml

Per calf-foal: 5 ml

Per horse: 10 ml

Per rabbit: 2 ml

Dilute in the drinking water or milk before administration. Administer freshly prepared solutions.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Not applicable

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 package: 30 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

None.

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 2008

15. OTHER INFORMATION**PACKAGES**

Aluminum bottles of 100 ml and 1000 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