

PACKAGE LEAFLET

For animal treatment only

ZINGUL injectable oily solution,
of Vitamin A, Vitamin D3, Vitamin E for horses, cattle, pigs, sheep, goats

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

ZINGUL

Injectable oily solution

Vitamin A, Vitamin D3, Vitamin E (50,000 IU + 25,000 IU + 50mg)/ml

for horses, cattle, pigs, sheep, goats

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 ml of solution contains:

Active substances:

Vitamin A (as palmitate) 50.000 IU

Vitamin D₃ 25.000 IU

Vitamin E (as acetate) 50 mg

Excipients: Butylhydroxytoluene, Butylhydroxyanisole, Benzyl alcohol, Myritol 318

4. INDICATIONS

ZINGUL is recommended for the treatment of vitamin A, D₃ and E deficiency in newborn and young animals. Also, for reduced fertility, developmental abnormalities of growth (rickets), supportive treatment during stressful situations, diarrhea and infectious diseases, as well as during pregnancy and lactation.

5. CONTRAINDICATIONS

Do not use in food producing animals with adequate vitamin A supply due to the possibility of accumulation in edible tissues

6. ADVERSE REACTIONS

There are no adverse reactions, when used according to instructions.

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, Sheep, Goats

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

Administered intramuscularly.

Adult Cattle, Horses:	7 - 15 ml
Calves, foal:	5 - 7 ml
Adult Sheep, Goats:	5 - 7 ml
Lambs, Kids:	3 - 5 ml
Adult Pigs:	5 - 7 ml
Piglets:	0.5 - 2 ml

This veterinary medicinal product should not be used by subcutaneous route of administration in food producing species.

In food producing species the veterinary medicinal product should be administered only once and the dose should not exceed the recommended limits.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIODS

Meat and Offal:

- Cattle: 231 days
- Pig: 200 days
- Horse: 231 days
- Sheep: 200 days
- Goat: 200 days

Milk: 120 hours (5 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 package: 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

Special warnings for each target species

None

Special precautions for use in animals:

Not applicable

Special precautions for use in animals

Not applicable

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

In case of accidental self-injection, a risk of hypervitaminosis in relation to vitamin A cannot be excluded. Therefore, administration should be performed with great caution. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Studies with vitamin A in laboratory animals have shown evidence of teratogenic effects. Therefore, this veterinary medicinal product should not be administered by pregnant women

Pregnancy:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation

Interaction with other medicinal products and other forms of interaction:

None known

Overdose (symptoms, emergency procedures, antidotes):

In case of accidental overdose, clinical symptoms of hypervitaminosis A and D will become apparent. In case of overdose, the fat-soluble vitamins, especially vitamin A, accumulates in the liver and this may be dangerous for humans (teratogenic effects on pregnant women).

Incompatibilities:

None 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

NOVEMBER 2021

15. OTHER INFORMATION

PACKAGES

Vial of 50ml and 100ml

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