PACKAGE LEAFLET

For animal treatment only

IVASEPT powder

for oral solution of Vitamin E acetate and Sodium selenite for Chicken

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 IVASEPT

powder for oral solution Vitamin E acetate, Sodium Selenite for Chicken

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

100 g of powder contains:

Active substances: 2 g Vitamin E acetate, 80 mg Sodium selenite **Excipients:** Lactose, BHT (B-HYDROXY-TOLUOLUM)

4. INDICATIONS

IVASEPT powder for oral sol. is indicated for the prevention and treatment of exudative diathesis, encephalomalacia and muscular dystrophy of chicken. Vitamin E and selenium are also required for the normal reproductive performance and for the hatchability of eggs.

5. CONTRAINDICATIONS

Do not administer to animals with hepatic and renal failure. Do not mix in the feed, because it is water soluble powder.

6. ADVERSE REACTIONS

None when used according to the 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

Chicken

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

100 g (1 sachet IVASEPT powder for oral sol / 100 L of drinking water for 3-5 days

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Chicken:

Meat and offal: 7 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25°C.

Shelf life after dilution or reconstitution according to instructions: 24 hours

Do not use this veterinary medicinal product after the expiry date which is stated on the foil sachet or container. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Selenium is toxic and the recommended dosage should not be exceeded.

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

FEBRUARY 2008

15. OTHER INFORMATION

PACKAGES

Sachet of 50 g, 100 g and 500 g Container of 1 kg and 5 kg 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