PACKAGE LEAFLET

For animal treatment only

IVASULF medicated premix 10%

Medicated premix of Sulfadimidine for pigs

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVASULF
medicated premix
Sulfadimidine 100g/kg
for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 kg of product contains:
Active substance: Sulfadimidine 100 g
Excipients: Maize oil, Rice hulls

4. INDICATIONS

For the prevention and treatment of pigs' atrophic rhinitis caused by *Bordetella bronchiseptica*.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

Long term administration of IVASULF premix 10% may cause haematological disorders. For this reason, pigs receiving IVASULF premix 10% for a long-term period should be monitored. Furthermore, treated animals may exhibit crystals in urine, should they become deprived of drinking water. Treat pigs with kidney failure with caution, as they are sensitive to long term use of IVASULF premix 10%.

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

Pigs

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

Sows: 1-1.5 kg IVASULF premix 10%/ tonne of final feed during the last month of gestation.
Piglets-Pigs: 1 kg IVASULF premix 10%/ tonne of final feed from the age of 2 weeks. Treat for up to 30 days. Long term use of IVASULF® premix 10% must be carefully supervised by the veterinary surgeon.

9. ADVICE ON CORRECT ADMINISTRATION

Special precautions for use in animals

Ensure that IVASULF premix 10% is homogenously mixed with the animals' feed. To ensure thorough dispersion of IVASULF® premix 10% in the final feed, it is advisable to first mix the recommended quantity of the premix with 10 kg of feed and then mix this quantity with the final feed. During IVASULF premix 10% provide animals with plenty of drinking water.

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

Avoid direct skin contact or inhalation of the powder.

10. WITHDRAWAL PERIOD

Pigs: Meat and offal: 28 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in ambient conditions.
Shelf life after incorporation into the feed: 3 months
Do not use this veterinary medicinal product after the expiry date which is stated on the foil sachet or sack. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

See section "ADVERSE REACTIONS"

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 1993

15. OTHER INFORMATION

PACKAGES
Alufoil sachet of 1 kg
Paper sack of 25 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