

PACKAGE LEAFLET

For animal treatment only

ERYTHROMYCIN/ PROVET 5% powder for oral solution for poultry (chicken and turkey)

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

ERYTHROMYCIN/PROVET

powder for oral solution

Erythromycin 5%

poultry (chicken and turkey)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

100 g of product contain:

Active substance: Erythromycin base (as thiocyanate) 5 g

Excipients: Flavor cinnamon oil, Amaranth (Dye red FD&C No 2), Sodium lauryl sulfate, Sodium citrate, Sugar granular

4. INDICATIONS

ERYTHROMYCIN/PROVET 5% powder for oral solution is recommended for the prevention and treatment of the following diseases of chickens and turkeys.

Chickens: chronic respiratory disease (C.R.D.), infectious coryza, pasteurellosis, infectious synovitis, staphylococcal and streptococcal infections

Turkeys: air sacculitis, blue comb, bursitis, erysipelas, pasteurellosis, staphylococcal and streptococcal infections

5. CONTRAINDICATIONS

Do not administer to laying hens producing eggs for human consumption.

6. ADVERSE REACTIONS

None known

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 (broilers) and Turkey

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

It is administered per os via the drinking water.

Erythromycin is generally administered to chickens and turkeys at the dose rate of 300-500 mg of active substance/ L of drinking water.

Prevention: Dilute 6 g ERYTHROMYCIN/PROVET 5% powder for oral solution/ L of drinking water for 3 days

Treatment: Dilute 10 g ERYTHROMYCIN/PROVET 5% powder for oral solution/ L of drinking water for 4-5 days

9. ADVICE ON CORRECT ADMINISTRATION

Wash hands after use.

10. WITHDRAWAL PERIOD

Chickens(broilers)-Turkeys: Meat: 24 hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store at temperatures below 25°C.

Shelf-life of the veterinary medicinal product after reconstitution: 24 hours

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

12. SPECIAL WARNINGS

Generally, macrolides should not be combined with lincosamides, as they compete for the same binding site. Erythromycin enhances the activity of warfarin and can reduce the corticosteroid levels.

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

JULY 2012

15. OTHER INFORMATION

PACKAGE

Sachet of 28 g and 227 g

Plastic sacks of 2 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