The following text is currently approved by the National Organization for Medicines (E.O.F.) in Greece and is subject to changes at any time.

PACKAGE LEAFLET

For animal treatment only

ERYTHROMYCIN/ PROVET 20%

powder for oral solution for poultry (chicken and turkeys)

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 ERYTHROMYCIN/ PROVET

powder for oral solution Erythromycin 20 % for chickens, turkeys

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

100 g of product contain: Active substance: 20 g Erythromycin base (as thiocyanate) Excipients: Sodium citrate, Sodium lauryl sulfate, Sugar granular

4. INDICATIONS

ERYTHROMYCIN/PROVET 20% 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, ROUTES AND METHOD OF ADMINISTRATION

It is administered per os via the drinking water.

The general dosage of erythromycin in broilers and turkeys is 300-500 mg of active substance/ L of water. <u>Prevention:</u> Dilute 1.25 g ERYTHROMYCIN/PROVET 20% powder for oral solution/ L of water for 3 days (half box of 500 g in 200 L of drinking water)

<u>Treatment:</u> Dilute 2.5 g ERYTHROMYCIN/PROVET 20% powder for oral solution/ L of water for 4-5 days (one box of 500 g in 200 L of drinking water)

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 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

<u>PACKAGE</u> Box of 500 g Metal box with plastic sack of 1 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