

PACKAGE LEAFLET

For animal treatment only

MYCO-VET powder for oral solution of Tylosin for Chicken and Turkey

1. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER AND OF THE MANUFACTURING AUTHORIZATION 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

MYCO-VET

powder for oral solution

100g/g

Tylosin

for Chicken and Turkey

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each 100 g container contains:

Active substance: 100 g Tylosin (as tartrate)

Excipients: none

4. INDICATIONS

MYCO-VET® powder for oral solution is indicated for the control of infections caused by *Mycoplasma synoviae* in chickens and *Mycoplasma gallisepticum* S6 in chickens and turkeys.

5. CONTRAINDICATIONS

None known

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, Turkey

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

Administer per os.

Treatment of mycoplasmosis

Broilers: MYCO-VET 0.5 g/ L of drinking water for 24-72 hours

Replacement chicks and chicken for reproduction-chicken for egg production:

MYCO-VET 0.5 g/ L of drinking water for 48-72 hours

Turkeys: MYCO-VET 0.5 g/ L of drinking water for 48-120 hours

9. ADVICE ON CORRECT ADMINISTRATION

Avoid direct contact with skin and mucus membranes.

10. WITHDRAWAL PERIOD

Chicken:

Meat & offal: 1 day

Eggs: 0 days

Turkey:

Meat & offal: 5 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store at temperature below 25°C.

Shelf life after dilution in the drinking water according to directions: 3 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

None

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

APRIL 2013

15. OTHER INFORMATION

PACKAGE

Container of 100 g

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