

**MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO
PACKAGE LEAFLET**

70g, 500g 1kg sachets.

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF
THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH
RELEASE, IF DIFFERENT**

Marketing Authorisation Holder:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Erythrocin 16.5 % w/w Soluble Powder for oral solution

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each sachet contains 16.5% w/w erythromycin (as erythromycin thiocyanate) and amaranth (E213).

4. PHARMACEUTICAL FORM

Soluble powder for oral solution

5. PACKAGE SIZE

70g, 500g, 1kg

6. INDICATION(S)

Chickens: For the treatment of Chronic Respiratory Disease caused by Mycoplasma infection for the following age ranges of birds:

Broilers up to 6 days of age.

Birds intended as replacement layers up to 6 days of age.

Broiler-Breeders of any age.

7. CONTRAINDICATIONS

Any medicated drinking water which is not consumed within 24 hours should be discarded

8. TARGET SPECIES

Chickens

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

For oral administration via the drinking water.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of erythromycin has to be adjusted accordingly.

For 70 g sachet:

Dosage:

1 sachet per 45 litres (10 gallons) of drinking water continuously for 1-5 days, depending on response (approximately 25.5 mg/kg Erythromycin bodyweight per day).

Mixing:

Slowly add the contents of the sachet to not less than 2.25 litres (1/2 gallon) of clean, cold drinking water, stirring continuously until dissolved completely. This solution should then be added to more drinking water to make up a total volume of 45 litres (10 gallons). Ensure that the inlet to the header tank is closed.

Ensure that the inlet to header tank is closed. The water system to which the product is added must be in good working order and the header tanks must be free of dust, algae or other particulate matter.

For larger sachets, 500 g and 1 kg:

Dosage:

Mix 100g Erythrocin soluble per 64 litres of drinking water and administer continuously for 1-5 days, depending on response (approximately 25.5 mg/kg Erythromycin bodyweight per day).

Mixing:

Slowly add 100 g to not less than 3.25 litres of clean, cold drinking water, stirring continuously until completely dissolved. This solution should then be added to more drinking water to make up a total volume of 64 litres. Ensure that the inlet to the header tank is closed.

10. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.

Chickens may be slaughtered for human consumption only after 6 days from the last treatment.

Eggs for human consumption must not be taken during treatment. Eggs for human consumption may be taken only after 6 days from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.. Do not use after the stated expiry date. At the end of the treatment, discard any unused product. Any medicated drinking water which is not consumed within 24 hours should be discarded.

12. SPECIAL WARNING(S)

SPECIAL WARNINGS FOR THE TARGET SPECIES: AUTIONS FOR USE IN ANIMALS:

Official, national and regional antimicrobial policies should be taken into account when the product is used.

Due to a lack of information on the fate and effects of erythromycin in the environment veterinary surgeons prescribing this product under the cascade should satisfy themselves that there will be no adverse impact on the environment.

USER WARNINGS:

Wash hands and exposed skin after use. Do not eat, drink or smoke whilst preparing the formulation or while animals are being treated. In case of contact with eyes, rinse immediately with clean water and seek medical advice if irritation persists.

13. EXPIRY DATE

14. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

15. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

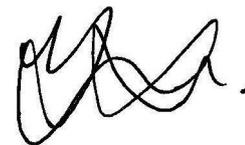
16. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children

17. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4000

18. MANUFACTURER’S BATCH NUMBER



Approved: 29 September 2022