SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Erythrocin 16.5 % w/w Soluble Powder for oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: **% w/w**

Erythromycin e.g. 16.5
(as erythromycin thiocyanate)

Excipients:

Amaranth (E123)

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Powder of oral solution.
Fine, homogenous pinkish-beige powder with a cinnamon odour.

4. CLINICAL PARTICULARS

4.1 Target species

Broilers up to 6 days of age.
Birds intended as replacement layers up to 6 days of age.
Broiler-Breeders of any age.

4.2 Indications for use

For the treatment of Chronic Respiratory Disease caused by Mycoplasma infection.

4.3 Contra-indications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

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

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.

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

Do not eat, drink or smoke while preparing the diluted 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. Wash hands and exposed skin after use.

4.6 Adverse reactions (frequency and seriousness)

None reported

4.7 Use during pregnancy, lactation or lay

Not applicable

4.8 Interaction with other medicinal products and other forms of interaction

None reported

4.9 Amounts to be administered and administration route

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:
1 sachet per 45 litres of drinking water continuously for 1-5 days, depending on response (approximately 25.5 mg/kg Erythromycin bodyweight per day). Slowly add the contents of the sachet to not less than 2.25 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 45 litres. Ensure that the inlet to the header tank is closed.

For larger sachets, 500 g and 1 kg:
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).
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.

4.10 Overdose (Symptoms, emergency procedures, antidotes)

No information available

4.11 Withdrawal periods

Chickens: 6 days.
Eggs: 6 days.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet code: QJ01FA01.

Erythromycin is a macrolide antibiotic with a bacteriostatic action against a wide range of bacteria, although it also has a bactericidal action against certain pathogenic organisms. It is highly active against gram-positive bacteria and at low concentrations it inhibits many other types of micro-organisms. In addition to the gram-positive bacteria, most strains of Neisseria and Haemophilus are sensitive as are some strains of Bordetella, Brucella, Pasteurella, Listeria, Actinomyces, Mycoplasma, Rickettsia, certain large viruses and Treponema pallidum.

Erythromycin exerts its effect only against multiplying bacteria. It inhibits protein synthesis by binding to 50 S ribosomal subunits of sensitive micro-organisms. Certain resistant micro-organisms with mutational changes in components of this subunit of the ribosome fail to bind the drug.

Erythromycin is absorbed rapidly when administered orally and diffusion occurs into most tissues and fluids. Elimination of erythromycin occurs primarily through hepatic metabolism and the remainder is excreted in active form in the urine and bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Amaranth (E123)
Cinnamon natural aroma

Sodium cyclamate
Sodium citrate dihydrate

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after dilution or reconstitution according to directions: 24 hours.

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place.
Any medicated drinking water not consumed within 24 hours should be discarded. At the end of the treatment, discard any unused product.

6.5 Nature and composition of immediate packaging

Polyethylene, Aluminium, and Polyethylene terephthalate sachets.
Contents = 70 g, 500 g and 1 Kg.

Not all pack size may be marketed.

6.6 Special precautions for the disposal of unused medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

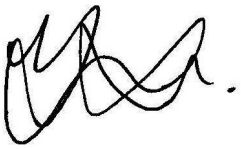
Vm 15052/4000

9. DATE OF FIRST AUTHORISATION

24 April 1996

10. DATE OF REVISION OF THE TEXT

September 2022



Approved: 29 September 2022