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

Each g of powder contains:

Active substance		
Erythromycin as erythromycin thiocyanate	16.5 %	w/w
Excipients		
Amaranth (E123)	0.35 %	w/w

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens.

4.2 Indications for use, specifying the target species

For the treatment of chronic respiratory disease caused by Mycoplasma infection where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates Erythromycin as the drug of choice.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

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.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For oral administration via the drinking water.
To ensure a correct dosage, body weight of birds to be treated should be determinated as accurately as possible.

70 g sachet
1 sachet per 45 litres of drinking water continuously for 1 to 5 days, depending on response (approximately 25.5 mg/kg bodyweight per day). Slowly add the contents of this sachet to not less than 2.25 litres of clean, cold drinking water, stirring continuously until dissolved completely. This solution should then be added to more drinking water to make up to a total volume of 45 litres. Ensure that the inlet to the header tank is closed.

500 g and 1 kg sachets
100 g erythrocin powder per 64 litres of drinking water continuously for 1 to 5 days, depending on response (approximately 25.5 mg/kg 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 to a total volume of 64 litres. Ensure that the inlet to the header tank is closed.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No information available.

4.11 Withdrawal period(s)

Eggs: 6 days
Meat and offal: 6 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, erythromycin.
ATCvet code QJ01FA01

5.1 Pharmacodynamic properties

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 micro-organisms.

The antibiotic 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.

In in-vitro studies, the action of erythromycin against gram-positive bacteria, as measured by the minimum inhibitory concentrations, appears to be comparable to that of penicillin.

The mode of action of erythromycin and other macrolide antibiotics is the inhibition of protein synthesis by binding to 50 S ribosomal subunits of sensitive micro-organisms. Certain resistant micro-organisms with mutational changes in components of this sub-unit of the ribosome fail to bind the drug.

5.2 Pharmacokinetic particulars

When erythromycin is absorbed in the rat, it is excreted in the bile. Also, in rats and dogs erythromycin is converted to des-N-methyl erythromycin and carbon dioxide.
In the rabbit, erythromycin is rapidly demethylated by a microsomal enzyme in the liver to yield des-N-methyl erythromycin and formaldehyde. The latter was derived from the N-methyl group of D-desosamine. With the exception of the adrenal gland, other tissues tested did not cause demethylation of the antibiotic.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Amaranth (E123)
Cinnamon Natural Aroma
Sodium Cyclamate
Sodium Citrate

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf-life after dilution: 24 hours.

6.4 Special precautions for storage

Store in a dry place below 25ºC.

6.5 Nature and composition of immediate packaging

Polyethylene/ aluminium and polyethyleneterephthalate sachets containing 70 g, 500 g and 1 kg.
Not all pack sizes may be marketed.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10815/061/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

March 2019