PROVEN ANTICOCCIDIAL WITH UNIQUE PROFILE

Amprol® 9,6% Oral Solution

INTRODUCTION

Throughout the world coccidiosis is the most significant disease for poultry producers. When considering treatment costs and lost performance, the disease costs the industry an estimated 5 billion dollars worldwide, making it the most expensive disease affecting the poultry industry today. Traditionally, the poultry industry has relied heavily on the use of anticoccidial medications to prevent or to treat the disease.

Amprol® was approved in USA in 1960 and is nowadays a product of interest, due to its good water solubility, safety and very good curing and preventing mode of action against coccidiosis in poultry.

Amprol® 9,6% oral solution is a water-soluble therapeutic product which is used for the treatment of coccidiosis in poultry, including broilers, replacements, laying hens, breeders and turkeys.





Structure and activity

Amprol® 9,6% oral solution is therapeutic to treat any outbreak of coccidiosis. It is effective against all *Eimeria* species in chickens such as: *E. acervulina, Eimeria maxima, Eimeria tenella, Eimeria brunetti, Eimeria praecox, Eimeria mitis* and *Eimeria necatrix*. In turkeys it can be used to treat outbreaks of coccidiosis with *Eimeria meleagrimitis, Eimeria adenoeides, Eimeria gallopavonis* and *Eimeria meleagridis*.

Mode of action

Amprolium, the active substance of Amprol® 9,6% oral solutions is a thiamine antagonist. The anticoccidial effect of Amprolium is achieved by inhibiting the *Eimeria spp.* to uptake thiamine. The thiamine requirement for *Eimeria spp.* is, compared to animals, relatively high and therefore Amprolium will cause starvation of the parasite because of thiamine deficiency. As this way is unique, Amprolium does not show cross-resistance with other anticoccidial preparations.



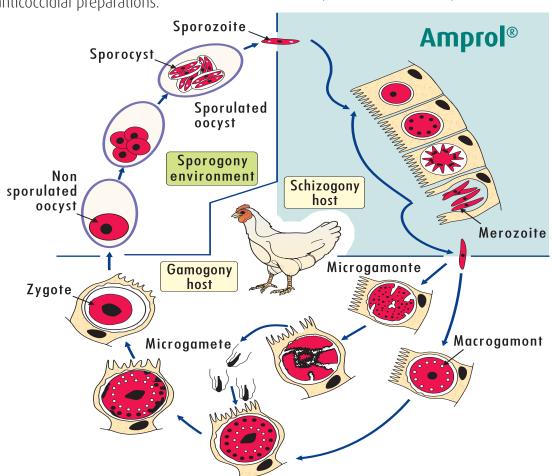




Indication for use

Amprol® 9,6% oral solution can be used through the lifecycle of birds from day old chicks through the day of slaughter and is effective to treat coccidiosis in broilers, breeders, replacement chickens, laying hens and turkeys.

Amprol® 9,6% oral solution does not interact with other coccidiostats and/or antibiotics and can be administered at any moment in the lifecycle of birds. Whenever an outbreak of coccidiosis in either broilers or layers occurs, Amprol® can be used without need to worry about withdrawal periods.



Disease

Coccidiosis is one of the biggest reasons of economic loss in the poultry industry. It is a parasitic disease, caused by Eimeria spp. which harms the intestinal tract of his host. Coccidia spp., are small parasites, called protozoas that can multiply in the epidermal cells of the intestines. There is no cross-resistance between different Eimeria species which means that after an outbreak with coccidiosis the flock can develop immunity to the exposed species of coccidia, but remains sensible to other species.

The reproduction of *Coccidia* in chickens depends on the species of *Eimeria* and for all species consists of sporulated oocysts, an asexual cycle with different generations followed by a sexual cycle resulting in shedding of non sporulated oocysts in the droppings. In the litter the oocysts will sporulate to an infectious form.

Efficacy

The efficacy of Amprol® 9,6% oral solution against coccidiosis has been proven under laboratory and field conditions.

Pharmacokinetics and dynamics

A development confirmed that over 90% of the Amprolium consumed by the bird remains in the intestines and is eliminated within 48 hours.

Safety

Amprol® 9,6% oral solution has been proven to be safe in poultry due to its high therapeutic index and it has been used safely in chickens and turkeys of all ages. Experience has also shown effective and safe use of Amprol® 9,6% oral solution in other species such as pheasants, partridges, quails and guinea fowl. A five-fold multiple of the highest approved dose produced no sign of toxicity. There is no known toxicity in non-target species at approved dose levels. Amprol® 9,6% oral solution at approved dose levels does not affect production in layers or broiler breeders.

Adverse reactions

No adverse reactions are observed.

Special warnings

If no improvement is noted within three days, have the diagnosis reconfirmed and follow the instructions of your veterinarian or poultry pathologist. Losses may result from intercurrent disease or other conditions affecting drug intake, which contribute to the virulence of coccidiosis under field conditions.



Withdrawal Period

The absorption, metabolism, elimination and the low toxicity of Amprol® got the European administration to include it in Annex II, the group of preparations, for which Maximum Residue Levels (MRLs) are not required (Official Journal of European Community, dated July 18, 2001). This allows specifying a withdrawal period of Amprolium of 0 days in regard to meat and eggs. This European decision is in compliance with the US legislation, where Amprol® is registered with withdrawal period of 0 days in regard to meat and eggs.

Amprol[®] with withdrawal period of 0 days is the only preparation, which can be used in broilers, turkeys and laying hens.

Dosages and mixing directions for using Amprol® 9,6 Oral Solution

Depending on the severity of the outbreak Amprol® 9,6 oral solution can be used in different dose levels in the drinking water ranging from 0.625 L of Amprol® 9,6 oral solution in 1000 L of water to 2.5 L of Amprol® 9,6 oral solution in 1000 L of water. Use the product for 3 to 5 days.

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Dose levels:

Severe infection: 2.5 L Amprol® 9,6 oral solution in 1000 L of water during 3-5 days

Moderate infection: 1.25 L Amprol® 9,6 oral solution in 1000 L of water during 3-5 days

Mild infection: 0.625 L Amprol® 9,6 oral solution in 1000 L of water during 3-5 days

First mix the amount of product in 10 L of water by thoroughly stirring, before adding it into the medication barrel. Always stir thoroughly.

Storage and Stability

Amprol® 9.6% oral solution is stable for five years from time of manufacture. Benzoic Acid is added as preservative. Always keep above 5°C.

Stock solutions for proportions may be stored in a clean, closed labeled container for up to three days.

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Packaging

Benefits

- Can be administered through drinking water
- Can be used safely in chickens and turkeys of all ages
- Safe in poultry due to its high therapeutic index
- 0 days withdrawal period in poultry according to EU and USA legislation authorities
- Minimum risk of residual substances for consumers.



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