SCIENTIFIC OPINION

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Safety and efficacy of Avatec® 150G (lasalocid A sodium) for chickens for fattening and chickens reared for laying, and modification of the terms of authorisation for chickens for fattening, chickens reared for laying, turkeys for fattening, minor avian species (pheasants, guinea fowl, quails and partridges) except laying birds

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Abstract

Avatec® 150G is an anticoccidial feed additive containing 15% of the active ingredient lasalocid A sodium, an ionophore anticoccidial. The tolerance study indicated that oral administration of lasalocid A sodium via feed at doses at and above the targeted lasalocid dose of 125 mg/kg was not tolerated in chickens for fattening. Consequently, no safe dose can be established by the tolerance study submitted. Concurrent administration of lasalocid with tiamulin and certain other medicinal substances should be avoided. Lasalocid sodium has a selective antimicrobial activity against Gram-positive bacterial species while many Enterobacteriaceae are naturally resistant. Induction of resistance and/or cross-resistance was not observed in experimental conditions. Lasalocid A sodium is not genotoxic and not carcinogenic. The newly conducted cardiovascular study in dogs indicated an acute no-observed-adverse-effect level (NOAEL) of 1 mg/kg body weight (bw) per day. Since this NOAEL is above the lowest NOAEL of 0.5 mg/kg bw per day previously identified in a 2-year toxicity study in rats and a developmental study in rabbits, it is concluded that this NOAEL (0.5 mg/kg bw per day) is an appropriate base for establishing an Acceptable Daily Intake of 0.005 mg lasalocid sodium/kg bw. The use of lasalocid A sodium from Avatec® 150G at the highest proposed level of 125 mg/kg complete feed is safe for the consumer. For compliance with the maximum residue limits (MRLs), a withdrawal period of 3 days is necessary. No risk for the user is expected from the use of Avatec® 150G. The use of lasalocid A sodium from Avatec® 150G in feed for chickens for fattening and chickens reared for laying up to the highest proposed dose does not pose a risk for the environment. Insufficient evidence of the anticoccidial efficacy of lasalocid A sodium was provided in chickens for fattening/reared for laying.

Keywords: Coccidiostat, Avatec, lasalocid A sodium, safety, efficacy, poultry

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Summary

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of Avatec® 150G (lasalocid A sodium) for chickens for fattening and chickens reared for laying. The FEEDAP Panel was also requested to assess the compliance with maximum residue limits (MRLs) established by Implementing Regulation (EU) No 1277/2014 for chickens for fattening, chickens reared for laying, turkeys for fattening and other minor avian species, except laying birds. In addition, the proposed reduction of the withdrawal period (from five to two days) is evaluated.

Avatec® 150G is an anticoccidial feed additive containing 15% of the active ingredient lasalocid A sodium, an ionophore anticoccidial. It is indicated for use for the control of coccidiosis in chickens for fattening, chickens reared for laying, turkeys and minor avian species (pheasants, guinea fowl, quails, and partridges other than laying birds).

The tolerance study indicated that oral administration of lasalocid A sodium via feed at doses at and above the targeted lasalocid dose of 125 mg/kg was not tolerated in chickens for fattening. Consequently, no safe dose can be established by the tolerance study submitted. Concurrent administration of lasalocid with tiamulin and certain other medicinal substances should be avoided.

Lasalocid sodium has a selective antimicrobial activity against Gram-positive bacterial species while many Enterobacteriaceae are naturally resistant. Induction of resistance and/or cross-resistance was not observed in experimental conditions.

Lasalocid A sodium is not genotoxic and is not carcinogenic. The newly conducted cardiovascular study in dogs indicated an acute no-observed-adverse-effect level (NOAEL) of 1 mg/kg body weight (bw) per day. Since this NOAEL is above the lowest NOAEL of 0.5 mg/kg bw per day previously identified in a 2-year toxicity study in rats and a developmental study in rabbits, it is concluded that this NOAEL (0.5 mg/kg bw per day) is an appropriate base for establishing an Acceptable Daily Intake of 0.005 mg lasalocid sodium/kg bw.

The use of lasalocid sodium from Avatec® 150G at the highest proposed level of 125 mg/kg complete feed in chickens and turkeys for fattening, in chicken reared for laying up to the 16th week of life and growing pheasants, partridges, quails and guinea fowl is safe for the consumer. For compliance with the MRLs, a withdrawal period of 3 days is necessary.

No risk for the user is expected from the use of Avatec® 150G in poultry nutrition.

The use of lasalocid sodium from Avatec® 150G in feed for chickens for fattening and chickens reared for laying up to the highest proposed dose does not pose a risk for the environment.

Insufficient evidence of the anticoccidial efficacy of lasalocid A sodium was provided in chickens for fattening/reared for laying. Regulation (EC) No 429/2008 requires three floor pen studies and three field studies supporting the control of coccidiosis by the additive. Such an effect could only be shown in two floor pen studies with 75 mg lasalocid A sodium/kg complete feed and three anticoccidial sensitivity tests (ASTs) with 100 mg lasalocid A sodium/kg complete feed.