

Date of Approval: September 29, 2020

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-528

Savalan[®] 60

(salinomycin sodium)

Type A medicated article to be used in the manufacture of Type C medicated feeds

Broiler, roaster and replacement (breeder and layer) chickens, and quail

Broiler, roaster and replacement (breeder and layer) chickens: Use Savalan[®] 60 to provide salinomycin sodium concentrations ranging from 40-60 g/ton (0.0044% to 0.0066%) for the prevention of coccidiosis in broiler, roaster and replacement chickens caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti* and *E. mivati*.

Quail: Use Savalan[®] 60 to provide salinomycin sodium concentrations of 50 g/ton (0.0055%) for the prevention of coccidiosis in quail caused by *Eimeria dispersa* and *E. lettyae*.

Sponsored by:

Pharmgate Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-528

B. Sponsor

Pharmgate Inc.
1800 Sir Tyler Dr.
Wilmington, NC 28405

Drug Labeler Code: 069254

C. Proprietary Name

Savalan® 60

D. Drug Product Established Name

salinomycin sodium

E. Pharmacological Category

Anticoccidial

F. Dosage Form

Type A medicated article to be used in the manufacture of Type C medicated feeds

G. Amount of Active Ingredient

60 g/lb

H. How Supplied

50 lb (22.68 kg) bags

I. Dispensing Status

Over-the-counter (OTC)

J. Dosage Regimen

Broiler, roaster and replacement (breeder and layer) chickens: Use Savalan® 60 to provide salinomycin sodium concentrations ranging from 40-60 g/ton (0.0044% to 0.0066%).

Quail: Use Savalan® 60 to provide salinomycin sodium concentrations of 50 g/ton (0.0055%).

Feed continuously as the sole ration.

K. Route of Administration

Oral

L. Species/Class

Broiler, roaster, and replacement (breeder and layer) chickens, and quail

M. Indications

Broiler, roaster and replacement (breeder and layer) chickens: Use Savalan[®] 60 to provide salinomycin sodium concentrations ranging from 40-60 g/ton (0.0044% to 0.0066%) for the prevention of coccidiosis in broiler, roaster and replacement chickens caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti* and *E. mivati*.

Quail: Use Savalan[®] 60 to provide salinomycin sodium concentrations of 50 g/ton (0.0055%) for the prevention of coccidiosis in quail caused by *Eimeria dispersa* and *E. lettyae*.

N. Reference Listed New Animal Drug (RLNAD)

Bio-Cox[®] 60; salinomycin sodium; NADA 128-686; Huvepharma EOOD

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Pharmgate Inc., was granted a biowaiver for the generic product Savalan[®] 60 (salinomycin sodium) Type A medicated article to be used in the manufacture of Type C medicated feeds. The generic drug product is a Type A medicated article to be used in the manufacture of Type C medicated feeds, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is Bio-Cox[®] 60 (salinomycin sodium) Type A medicated article to be used in the manufacture of Type C medicated feeds, sponsored by Huvepharma EOOD, under NADA 128-686 and, was approved for use in broiler, roaster and replacement (breeder and layer) chickens, and quail on July 5, 1983.

III. HUMAN FOOD SAFETY

The tolerances for residues and withdrawal periods established for the RLNAD apply to the generic product. The following are assigned to this product for chickens and quail:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of salinomycin is 5 µg/kg of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. A tolerance is not required for salinomycin in edible tissues (excluding eggs) of chicken or quail under 21 CFR 556.592.

B. Withdrawal Period

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. No withdrawal period (or zero withdrawal) is required for salinomycin in chicken or quail.

C. Analytical Method for Residues

Because a tolerance for salinomycin residues is not required in chicken or in quail tissues (21 CFR 556.592), there is no official method for salinomycin sodium residues.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Savalan® 60:

Not for human use.

Warning: When mixing and handling Savalan 60 premix, use protective clothing, impervious gloves, eye protection and an approved dust respirator. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water.

V. AGENCY CONCLUSIONS

This information submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that Savalan® 60 when used according to the label, is safe and effective for the indications listed in Section I.M. above.

Additionally, data demonstrate that residues in food products derived from broiler, roaster and replacement (breeder and layer) chickens, and quail treated with Savalan® 60 will not represent a public health concern when the product is used according to the label.