

MAR 23 1999

Date of Approval _____

FREEDOM OF INFORMATION SUMMARY

For the removal of large roundworms (*Ascaridia spp.*) from turkeys, chickens, and large roundworms (*Ascaris summ*) and nodular worms (*Oesophagostomum spp.*) from swine.

Fleming Laboratories
Charlotte, NC 28234

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

NADA Number 10-005

Sponsor: Fleming Laboratories
Charlotte, NC 28234

Generic Name: Piperazine dihydrochloride
Piperazine dipiperazine sulfite

Trade Name: Wazine®, Pig Wormer

Marketing Status: OTC

II. INDICATIONS FOR USE:

Chickens, and turkeys: *Ascaridia spp.*

Swine: *Ascaris summ* and
Oesophagostomum spp.

III. A. DOSAGE FORM:

Soluble powder & liquid

B. ROUTE OF ADMINISTRATION:

Oral

C. RECOMMENDED DOSAGES:

Chickens: 50 milligrams per bird under 6 weeks of age; 100 milligrams per bird over 6 weeks of age.

Turkeys: 100 milligrams per bird up to 12 weeks of age; 200 milligrams per bird over 12 weeks

Swine: 50 milligrams per pound body weight.

IV. ANIMAL EFFECTIVENESS: The drug was the subject of National Academy of Science/National Research Council (NAS/NRC) reports which were published in the FEDERAL REGISTER of February 14, 1969 (34 FR 2213). The Academy evaluated these products as 'effective' for an anthelmintic for dogs, cats, chickens, turkeys, horses, swine, sheep and cattle.

- V. **ANIMAL SAFETY:** No further safety data are required
- VI. **HUMAN FOOD SAFETY:** Generally, NAS/NRC evaluation of a drug is concerned only with the effectiveness and safety of the drug for the treated animal. FDA's approval of this supplemental application providing for DESI-finalization also required that the product carry the proper human food safety warning and caution statements. Therefore, the supplemental application did involve a reaffirmation of the human safety data, establishment of a tolerance and assignment of withdrawal periods.

Piperazine is a low molecular weight secondary amine that is used in human medicine to treat ascariasis (roundworms) and enterobiasis (pinworm). The oral dosage for treating enterobiasis in humans is 65 mg/kg/day for seven consecutive days with a maximum daily dose of 2.5 g. This dosing regimen is routinely repeated two weeks after the first. Extrapolation between the short-term therapeutic use in humans and chronic lifetime exposure can be handled by assuming that a threshold for activity exists and applying a large safety factor to the therapeutic dose.

The residue data in Master File No. 3527, Jefferson Chemical Company, show that, following treatment of food-producing animals with piperazine, relatively high levels of total residues are incurred in tissues. The metabolism data also show that these residues deplete relatively quickly, and there is evidence that piperazine may be metabolized into endogenous substances. Thus, at longer withdrawal times, much of the residue present may be of no toxicological concern. Together, these data indicate that a period of withdrawal prior to slaughter should be observed with the use of piperazine in chickens, turkeys, and swine.

Currently there is no validated analytical method available to measure the depletion of parent piperazine in tissues of food-producing animals. However, the residue studies with radiolabeled piperazine in Master File 3527 indicate that withdrawal periods of two to three weeks should be ample to assure depletion of drug related residues to below levels of concern. Withdrawal times of 14 days for poultry and 21 days for swine are acceptable.

Under 21 CFR 556.1(a)(2), if it is not possible to determine a finite tolerance, but the agency believes that residues will be present in edible tissues, a negligible tolerance is required. Thus, given the available information on piperazine, it is recommended that a tolerance of 0.1 ppm parent piperazine base be established for all edible tissues. Assuming a person consumes 300 g of muscle tissue containing 0.1 ppm of piperazine, they will be exposed to a dose that is 13,000 times lower than the therapeutic dose that is well tolerated in humans. A tolerance of 0.1 ppm piperazine base is established for all tissues of poultry and swine.

VII. AGENCY CONCLUSIONS:

This supplemental NADA satisfied the requirements of section 512 of the Act and demonstrates that Piperazine wormer when used under its proposed conditions of use, is safe and effective for the labeled indications. The approval provides for use of piperazine for use as an anthelmintic in chickens, turkeys and swine.

The 'effective' finding of the NAS/NRC regarding piperazine which was published in the FEDERAL REGISTER of February 14, 1969, was subsequently reviewed by FDA with respect to the claims noted in the paragraph above. The firm submitted revised labeling to conform and, therefore, this supplemental NADA complies with the NAS/NRC evaluation and FDA's conclusions.

When NADA 10-005 was reviewed under NAS/NRC/DESI program, it was an over-the-counter product and this marketing status remains unchanged. Other piperazine products are also currently on the market as over-the-counter products. Therefore the Center for Veterinary Medicine has concluded that this product should retain over-the-counter marketing status.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), these changes are Category II changes. The approval of these changes is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. However, the new tolerance and withdrawal periods did require a reevaluation of the human food data in the parent application.

VIII. Labeling

Wazine 17

Piperazine Dihydrochloride Powders

Pig Wormer 17

Wazine Soluble

Pig Wormer Soluble

and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: February 7, 1969.

HERBERT L. LEY, Jr.,
Commissioner of Food and Drugs.

[F.R. Doc. 69-1901; Filed, Feb. 13, 1969;
8:45 a.m.]

PHENYRAMIDOL HYDROCHLORIDE, PHENYRAMIDOL SALICYLATE, AND PHENYRAMIDOL HYDROCHLORIDE WITH ALUMINUM ASPIRIN

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, on the following drugs marketed by Neisler Laboratories, Inc., Subsidiary of Union Carbide Corp., 434 North Morgan Street, Decatur, Ill. 62525:

1. Analexin 400 Capsules; 400 milligrams of phenyramidol hydrochloride per capsule (NDA 11-946).
2. Analexin-AF Tablets; 100 milligrams of phenyramidol hydrochloride and 300 milligrams of aluminum aspirin per tablet (NDA 12-146).
3. Analexin Tablets; 200 milligrams of phenyramidol hydrochloride per tablet (NDA 11-946).
4. Analexin Syrup; 100 milligrams of phenyramidol salicylate per 5 cubic centimeters (NDA 12-584).

These drugs continue to be regarded as new drugs. The effectiveness classification and marketing status of the drugs are described below.

PHENYRAMIDOL HYDROCHLORIDE; PHENYRAMIDOL SALICYLATE; PHENYRAMIDOL HYDROCHLORIDE WITH ALUMINUM ASPIRIN

A. Effectiveness classification. The National Academy of Sciences—National Research Council has evaluated these drugs as possibly effective for use for the relief of pain in a variety of acute, recurring, and chronic painful conditions; for the relief of pain associated with acute musculoskeletal disorders; with otitis media and sore throat; and with inflammatory processes and/or fever. The Food and Drug Administration concurs that substantial evidence of effectiveness is needed to support these indications.

B. Marketing status. 1. Holders of previously approved new-drug applications and any person marketing these drugs without approval will be allowed 6 months from the date of publication of this announcement in the FEDERAL REGISTER to obtain and to submit in a supplemental or original new-drug application data to provide substantial evidence of effectiveness of the drugs for those indications for which the drugs have been classified as possibly effective.

2. At the end of the 6-month period, any such data will be evaluated to determine whether there is substantial evidence of the effectiveness of the drugs for such uses. After that evaluation, the conclusions concerning the drugs will be published in the FEDERAL REGISTER. If no studies have been undertaken or if the studies do not provide substantial evidence of effectiveness, procedures will be initiated to withdraw approval of the new-drug applications for phenyramidol hydrochloride, phenyramidol salicylate, and

phenyramidol hydrochloride with aluminum aspirin, pursuant to the provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act. Withdrawal of approval of the applications will cause any such drugs on the market to be new drugs for which an approval is not in effect.

The above-named holder of the new-drug applications for these drugs has been mailed a copy of the NAS-NRC reports. Any interested person may obtain a copy of these reports by writing to the office named below.

Communications forwarded in response to this announcement should be directed to the attention of the following appropriate office and addressed to the Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204:

Requests for NAS-NRC reports: Press Relations Office (CE-300).

Supplements: Office of Marketed Drugs (MD-300), Bureau of Medicine.

Original new-drug applications: Office of New Drugs (MD-100), Bureau of Medicine. Comments on this announcement: Special Assistant for Drug Efficacy Study Implementation (MD-16), Bureau of Medicine.

This notice is issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: February 7, 1969.

HERBERT L. LEY, Jr.,
Commissioner of Food and Drugs.

[F.R. Doc. 69-1903; Filed, Feb. 13, 1969;
8:45 a.m.]

PIPERAZINE

Drugs for Veterinary Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, on the following preparations:

1. Asca-R, Tablets; contains 7.0 grains of piperazine adipate per tablet; marketed by Carson Chemicals, Inc., Box 466, New Castle, Ind. 47362.
2. Piperazine Adipate Powder; contains 37 percent piperazine base; marketed by Carson Chemicals, Inc.
3. Liquid-Rid (liquid); contains 17 percent piperazine base; marketed by Hess & Clark, Division of Richardson-Merrell, Inc., Ashland, Ohio 44805.
4. Purina Liquid Wormer; contains 16 percent piperazine base; marketed by Ralston Purina Co., St. Louis, Mo. 63102.
5. Wazine Liquid; contains 16.9 grams of piperazine (as sulfate) per 100 cubic centimeters; marketed by Salsbury Laboratories, 500 Gilbert Street, Charles City, Iowa 50616.
6. Wazine 300; contains 52.9 grams of piperazine (as sulfate) per 100 cubic centimeters; marketed by Salsbury Laboratories.
7. Wazine Soluble; contains 240 grams of piperazine (as dihydrochloride)

per pound; marketed by Salsbury Laboratories.

8. Pig Wormer; contains 16.9 grams of piperazine (as sulfate) per 100 cubic centimeters; marketed by Salsbury Laboratories.

The Food and Drug Administration concurs with the conclusions of the Academy that these drugs are effective as an anthelmintic for dogs, cats, chickens, turkeys, horses, swine, sheep, and cattle.

Supplemental new-drug applications are invited to revise the labeling provided in new-drug applications for these drugs to limit the claims and present the conditions of use substantially as follows:

INDICATIONS

Indicated for the removal of the listed parasites from the following species:

Chickens and turkeys: *Ascaridia spp.*
Dogs and cats: *Toxocara canis* and *Toxascaris leonina*.

Horses: *Ascarids (Parascaris equorum)*, strongyles (*Strongylus vulgaris*), small strongyles, and pinworms (*Oxyuris equi*).

Swine: *Ascaris lumbricoides* and *Oesophagostomum spp.*

Sheep: *Oesophagostomum spp.*

Cattle: *Neoscaris vitulorum* and *Oesophagostomum spp.*

DOSAGE AND ADMINISTRATION—PIPERAZINE BASE

1. Individual 1-day treatment; may be repeated when indicated:

Cats and dogs: 20-30 milligrams per pound body weight.

Horses: 50 milligrams per pound body weight.

Sheep: 60 milligrams per pound body weight.

Cattle: 37 milligrams per pound body weight for treatment of *Neoscaris vitulorum*; 70 milligrams per pound body weight for treatment of *Oesophagostomum spp.*

Swine: 60 milligrams per pound body weight.

Chickens: 50 milligrams per bird under 6 weeks of age; 100 milligrams per bird over 6 weeks of age.

Turkeys: 100 milligrams per bird up to 12 weeks of age; 100-400 milligrams per bird over 12 weeks of age according to size.

2. For herd and flock treatment (as the sole source of feed or water):

Swine: 0.2-0.4 percent in feed or 0.1-0.2 percent in water 1-2 days.

Turkeys and chickens: 0.2-0.4 percent in feed or 0.1-0.2 percent in water 1-2 days.

Directions for use in feed or water should assure that the amount of feed or water consumed will furnish in 1 day the required amounts of piperazine base per bird or per pound body weight of the animals eating or drinking the medicated ration.

This evaluation of these drugs is concerned only with their effectiveness and safety to the animal to which they are administered. It does not take into account the safety for food use of food derived from drug-treated animals. Nothing in this announcement will constitute a bar to further proceedings with respect to questions of safety of the drugs or their metabolites as residues in food products derived from treated animals.

This announcement is published (1) to inform the holders of new-drug applications of the findings of the Academy and of the Food and Drug Administration and (2) to inform all interested persons

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NDC 15565-201-24

FLEMING
Pig-Wormer Soluble
PIPERAZINE WORMER

FOR THE REMOVAL OF
LARGE ROUNDWORMS
(*Ascaris suum*)
AND NODULAR WORMS
(*Oesophagostomum* spp.)
FROM SWINE

For use in drinking water or feed.

ACTIVE DRUG INGREDIENT:

Piperazine Dihydrochloride
(Piperazine base: 51% or 230 grams per bag)

This bag will worm 4,600 lb. of swine herd
Weight.

**CAUTION: Keep out of Reach of Children.
For animal use only.
See reverse side.**

Manufactured by
FLEMING LABORATORIES, INC.
Charlotte, NC 28234

NET WT: 454 GRAMS (16 OZ.)

FDA Approved NADA 10-005

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DIRECTIONS FOR WORMING SWINE

The following dosage schedules are based on 50 milligrams of piperazine base per pound of body weight. It is recommended that the entire contents of this package be used at one time.

FOR WATER: Dissolve the contents of this bag (16 oz.) in water as shown in the following chart.

Animal Weight	No. of Animals Medicated	Amount Medication	Amount Water
25 lb.	184	1 bag	50 gal.
50 lb.	92	1 bag	50 gal.
75 lb.	61	1 bag	50 gal.
100 lb.	46	1 bag	50 gal.
150 lb.	31	1 bag	50 gal.
200 lb.	23	1 bag	50 gal.

FOR FEED: To formulate a wormer feed, mix Pig-Wormer Soluble at the rate of 1 bag per 200 lbs. of complete ration. Then 5 lb. of this wormer feed will worm 115 lb. of swine herd weight.

Worm every 30 days to break the large roundworm life cycle; worm sows and gilts before farrowing; boars at any time, pig 1 week after weaning and every 30 days thereafter.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism

FOR USE IN AUTOMATIC PROPORTIONERS: Dissolve each bag in 50 fl. oz. (1-1/2 quarts) of water to make a stock solution. Set proportioner to deliver 1 fl. oz. (30 ml) per gallon of drinking water, so that each bag of Pig-Wormer Soluble medicates 50 gallons of water which will treat 4600 lbs. of swine herd weight.

NOTE: Give the mediated feed or water as the only source of feed or drinking water until all is consumed. Provide sufficient feeders or waterers so all animals may eat or drink. When worming through water, best results are obtained by withdrawing the regular water supply the preceding evening then give Pig-Wormer Soluble in the first drinking water in the morning. Continue until the recommended amount is consumed, which should require one day or less. Do not withhold water during hot weather.

CAUTION: Do not give to sick, feverish, underweight, or physically weak animals.

WARNING: Withdraw medication prior to slaughter as follows:

Swine - 21 days

(FRONT OF BAG)

NDC 15565-201-24

Wazine[®] Soluble

**Piperazine wormer for
Turkeys, chickens, swine**

For use in drinking water or feed.

For removing large roundworms from turkeys and chickens (*Ascaridia* spp.), or swine (*Ascaris suum*), and nodular worms (*Oesophagostomum* spp.) from swine.

ACTIVE DRUG INGREDIENT:

Piperazine dihydrochloride
(Piperazine base: 51% or 230 grams per pound)

**CAUTION: Keep out of reach of children.
For animal use only.
See reverse side.**

Fleming Laboratories, Inc.
Charlotte, North Carolina 28234

NET WT. 454 GRAMS (16 OZ.)

FDA Approved NADA 10-005

(BACK OF BAG)

Wazine Soluble

DIRECTIONS: Wazine Soluble may be given by either the drinking water or the feed according to the dosages below. Starting in the morning, give the required quantity of medicated water or feed as the sole source of water/feed until consumed, which should require 1 day or less. Withdraw non-medicated water or feed the evening before giving medicated water/feed. Do not withhold water during hot weather. Provide sufficient watering or feeding space so that all birds/pigs have access to medicated water/feed. It is recommended that the entire contents of this package be used at one time.

TURKEYS One bag of Wazine Soluble will treat turkeys as follows:

Age	Turkeys	Water	Feed	Piperazine Base/Bird
Under 12 wks	2300	50 gal	200 lb.	100 mg
Over 12 wks	1150	50 gal	200 lb.	200 mg

Worm turkeys at 8, 12, 16 and 20 weeks of age.

CHICKENS One bag of Wazine Soluble will treat chickens as follows:

Age	Chickens	Water	Feed	Piperazine Base/Bird
Under 6 wks	4600	50 gal	200 lb.	50 mg
Over 6 wks	2300	50 gal	200 lb.	100 mg

Worm replacement pullets at 8, 12, and 16 weeks of age, and broilers at 4 and 6 weeks of age.

SWINE One bag of Wazine Soluble will treat 4600 lbs. live weight providing 50 mg piperazine base per pound of body weight (*Examples: 92 50-lb. pigs or 30 150-lb. pigs, etc.*). Mix each bag with 50 gallons of water or 200 lbs. of feed.

In general, worm swine every 30 days. Worm sows and gilts before breeding and up to 2 weeks before farrowing; boars at any time; and pigs one week after weaning and every 30 days thereafter.

For use in automatic water proportioners: Dissolve each bag in 50 fl. Oz. (1-1/2 quarts) of water to make a stock solution. Set proportioner to deliver 1 fl. Oz. (30 ml) per gallon of drinking water, so that each bag of Wazine Soluble medicates 50 gallons of water.

Caution: Do not give product to sick, feverish, underweight or physically weak birds or pigs.

WARNING: Withdraw medication prior to slaughter as follows:

Chickens -14 days
Turkeys -14 days
Swine -21 days

Do not use in chickens producing eggs for human consumption.

• **Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.**

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WAZINE[®] SOLUBLE

LOMBRICIDA

(PIPERAZINA CLORURODIHIDRATADA)

NDC 59448-201-21

Vermifugo para el uso en el control de gusanos largos redondos (*Ascaridia* spp.) en pollos y pavos; gusanos redondos (*Ascaris suum*) y gusanos modulares (*Oesophagostomum* spp.) en cerdos.

PARA USO EN EL AGUA

INGREDIENTE ACTIVO: ESTE PAQUETE CONTIENE PIPERAZINA CLORURODIHIDRATADA EQUIVALENTE A 58 GRAMOS DE PIPERAZINA BASE.

PARA USO ORAL EN ANIMALES SOLAMENTE

NO PARA CONSUMO HUMANO, MANTENGASE FUERA DEL ALCANCE DE LOS NIÑOS. EVITE EL CONTACTO DE ESTE PRODUCTO CON LOS OJOS. EN CASO DE ACCIDENTE LAVE LOS OJOS CON AGUA ABUNDANTE Y CONSULTE A SU MEDICO.

MANUFACTURADO POR
FLEMING LABORATORIES, INC.
CHARLOTTE, NC 28234

PESO NETO: 113.5 GRAMOS (4 ONZAS)

FDA NADA Aprobado 10-005

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INSTRUCCIONES PARA SU USO

POLLOS Y PAVOS:

Mezcle el contenido de este paquete de 4 onzas (113.5g) de Piperazina con 15 galones de agua para medicar uno de los siguientes:

- A. 1150 pollos menores de 6 semanas
- B. 575 pollos mayores de 6 semanas
- C. 575 pavos menores de 12 semanas
- D. 285 pavos mayores de 12 semanas

CERDOS:

Mezcle el contenido de este paquete de 4 onzas (113.5g) de Piperazina con 15 galones de agua para medicar uno de los siguientes:

- A. 56 cerdos de 20 libras de peso
- B. 22 cerdos de 50 libras de peso
- C. 11 cerdos de 100 libras de peso
- D. 7 cerdos de 150 libras de peso
- E. 6 cerdos de 200 libras de peso

MEDICADORES DE AGUA AUTOMATICOS PARA POLLOS Y PAVOS:

Mezcle el contenido de este paquete de 4 onzas (113.5g) en 12 onzas (3/4 pint) de agua. Ponga estas 12 onzas de solución en el medicador automático y ajuste el mismo a razón de una onza de solución por galón de agua. De esta manera medicará 12 galones de agua.

INFORMACION GENERAL

Para mejores resultados remueva el agua durante la tarde si la temperatura no está alta, y provea el agua medicada la próxima mañana. Permita que se consuma toda el agua.

Desparasite pollos y pavos de 4-6 semanas de edad, repita el tratamiento mensualmente o cuando sea necesario.

Desparasite cerdos todo 30 días, repita el tratamiento mensualmente o cuando sea necesario.

Desparasite cerdas jóvenes y adultas un mes antes del empadronamiento y un mes antes de parir.

No desparasite animales enfermos, con fiebre, bajos en peso o débiles.

AVISO: Retirar medicación antes de la mantanza:

- Polos - 14 días
- Pavos - 14 días
- Cerdos- 21 días

No usar de la pollos producir heuvos para consumo humano.

CONSULTE A SU VETERINARIO PARA ASISTENCIA EN EL DIAGNOSTICO, TRATAMIENTO Y CONTROL DE LOS PARASITOS.

TOME TIEMPO: OBSERVE LAS INSTRUCCIONES EN LA ETIQUETA.

NDC 15565-201-31

WAZINE® SOLUBLE

Piperazine wormer for
turkeys, chickens,
swine

For use in drinking water or feed.

For removing large roundworms from turkeys, chickens (*Ascaridia* spp.), or swine (*Ascaris suum*), and nodular worms (*Oesophagostomum* spp.) from swine.

Active drug ingredient:

Piperazine dihydrochloride
(Piperazine base: 51% or 230 grams per pound)

**Caution: Keep out of reach of children.
For animal use only.**

FLEMING LABORATORIES, INC.
Charlotte, NC 28234

NET WT. 50 kilos (110 POUNDS)

FDA Approved NADA 10-005

DIRECTIONS:

Mix Wazine Soluble required (see below) with required quantity of drinking water (or feed). Starting in the morning, give as the sole source of water (or feed) until all mediated water (or feed) is consumed, which should require 1 day or less. Withdraw non-medicated water (except during hot weather) or feed the evening before giving medication. Provide sufficient watering or feeding space so that all birds/pigs have access to medicated water/feed.

TURKEYS: One pound of Wazine Soluble will treat turkeys as follows:

Age	Turkeys	Water	Feed	Piperazine Base/Bird
Under 12 wks	2300	50 gal	200 lb.	100 mg
Over 12 wks	1150	50 gal	200 lb.	200 mg

Worm turkeys at 8, 12, 16 and 20 weeks of age.

CHICKENS: One pound of Wazine Soluble will treat chickens as follows:

Age	Chickens	Water	Feed	Piperazine Base/Bird
Under 5 wks	4600	50 gal	200 lb	50 mg
Over 6 wks	2300	50 gal	200 lb	100 mg

*Worm replacement pullets at 8, 12, 16 weeks of age,
and broilers at 4 and 6 weeks of age.*

SWINE One pound of Wazine Soluble will treat 4600 lbs. live body weight, providing 50 mg Piperazine Base per pound of body weight. Mix each bag with 50 gallons of water or 200 lbs. of feed. In general, worm swine every 30 days to break the large roundworm life cycle. Worm sows and gilts before breeding and up to 2 weeks before farrowing; boars at any time, and pigs 1 week after weaning and every 30 days thereafter.

For use in automatic water proportioners: Dissolve each pound of Wazine Soluble in 50 oz. (1½ quarts) of water to make a stock solution. Set proportioner to deliver 1 fl. oz. (30 ml) per gallon of drinking water, so that each pound of Wazine Soluble medicates 50 gallons of drinking water.

CAUTION: Do not give product to sick, feverish, underweight or Physically weak birds or animals.

WARNING: Withdraw medication prior to slaughter as follows:

Chickens - 14 days
Turkeys - 14 days
Swine - 21days

Do not use in chickens producing eggs for human consumption.

Consult your veterinarian for assistance in diagnosis, treatment, and control of parasitism.

NDC 15565-340-14

Wazine® -34

Piperazine Wormer

For the removal of large roundworms (*Ascaridia* spp.) from turkeys, chickens, and large roundworms (*Ascaris suum*) and nodular worms (*Oesophagostomum* spp.) from swine

ACTIVE DRUG INGREDIENT:

Each 100 ml contains 34 grams piperazine base (present as sulfate)

INGREDIENTS:

Water, color, flavoring, preservatives and stabilizer.

**CAUTION: Keep out of reach of children.
For animal use only.**

NET CONTENTS 3.785 Liters (1 gal)

FLEMING LABORATORIES, INC.

FDA Approved NADA 10-005

One gallon (3.8 liters) provides 1 treatment for:

12,800 turkeys up to 12 weeks of age, or
6,400 turkeys over 12 weeks of age, or
25,600 chickens 4 to 6 weeks of age, or
12,800 chickens over 6 weeks of age, or
1,024 25-lb. (11.4 kg) pigs, or
512 50-lb. (22.7 kg) pigs, or
256 100-lb. (45.5 kg) pigs, or
128 200-lb. (90.9 kg) pigs.

DIRECTIONS:

For best results, remove water in the evening (except during hot weather). Then, early the next morning, give Wazine-34 in the drinking water. Provide medicated water only, distributed in waterers sufficient in number so that all birds or animals have access to the water. The medicated water should be consumed in 1 day or less. Worming every 30 days helps break the large roundworm life cycle.

Turkeys

Under 12 weeks of age: For each 1,000 birds, use 10 fluid ounces (300 ml) of Wazine-34 in 20 U.S. gallons (76 liters) of drinking water.

Over 12 weeks of age: For each 1,000 birds, use 20 fluid ounces (600 ml) of Wazine-34 in 40 U.S. gallons (150 liters) of drinking water.

Treat turkeys at 8, 12, 16, and 20 weeks of age.

Chickens

4 to 6 weeks of age: For each 1,000 birds, use 5 fluid ounces (150 ml) of Wazine-34 in 10 U.S. gallons (38 liters) of drinking water.

Over 6 weeks of age: For each 1,000 birds, use 10 fluid ounces (300 ml) Wazine-34 in 20 gallons (76 liters) drinking water. Treat replacement pullets at 8, 12, and 16 weeks of age. Treat broiler chicks at 4 and 7 weeks of age.

Swine

For each 100 lb. (45.45 kg) of herd weight: Give ½ fluid ounce (15 ml) of Wazine-34 per U.S. gallon (3.8 liters) of drinking water. Treat sows and gilts before breeding and up to 2 weeks before farrowing; treat boars at any time; and treat pigs 1 week after weaning and every 30 days thereafter.

For use in automatic water proportioners: Mix 1 part Wazine-34 with 1 part water and set proportioner to deliver 1 fluid ounce (30 ml) per gallon of drinking water and give for 1 day.

Caution: Do not give to sick, feverish, underweight, or physically weak birds or animals.

WARNING: Withdraw medication prior to slaughter as follows:

Chickens - 14 days
Turkeys - 14 days
Swine - 21 days

Do not use in chickens producing eggs for human consumption.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Store above 32°F (0°C).
FLEMING LABORATORIES, INC.
Charlotte, NC 28234 USA

NDC 15565-340-16

Wazine[®] -34

Piperazine Wormer

For the removal of large roundworms (*Ascaridia* spp.) from turkeys, chickens, and large roundworms (*Ascaris suum*) and nodular worms (*Oesophagostomum* spp.) from swine

ACTIVE DRUG INGREDIENT:

Each 100 ml contains 34 grams piperazine base (present as sulfate)

INGREDIENTS:

Water, color, flavoring, preservatives and stabilizer.

**CAUTION: Keep out of reach of children.
For animal use only.**

NET CONTENTS 18.925 Liters (5 gal)

FLEMING LABORATORIES, INC.

FDA Approved NADA 10-005

One gallon (3.8 liters) provides 1 treatment for:

12,800 turkeys up to 12 weeks of age, or
6,400 turkeys over 12 weeks of age, or
25,600 chickens 4 to 6 weeks of age, or
12,800 chickens over 6 weeks of age, or
1,024 25-lb. (11.4 kg) pigs, or
512 50-lb. (22.7 kg) pigs, or
256 100-lb. (45.5 kg) pigs, or
128 200-lb. (90.9 kg) pigs.

DIRECTIONS:

For best results, remove water in the evening (except during hot weather). Then, early the next morning, give Wazine-34 in the drinking water. Provide medicated water only, distributed in waterers sufficient in number so that all birds or animals have access to the water. The medicated water should be consumed in 1 day or less. Worming every 30 days helps break the large roundworm life cycle.

Turkeys

Under 12 weeks of age: For each 1,000 birds, use 10 fluid ounces (300 ml) of Wazine-34 in 20 U.S. gallons (76 liters) of drinking water.

Over 12 weeks of age: For each 1,000 birds, use 20 fluid ounces (600 ml) of Wazine-34 in 40 U.S. gallons (150 liters) of drinking water.

Treat turkeys at 8, 12, 16, and 20 weeks of age.

Chickens

4 to 6 weeks of age: For each 1,000 birds, use 5 fluid ounces (150 ml) of Wazine-34 in 10 U.S. gallons (38 liters) of drinking water.

Over 6 weeks of age: For each 1,000 birds, use 10 fluid ounces (300 ml) Wazine-34 in 20 gallons (76 liters) drinking water. Treat replacement pullets at 8, 12, and 16 weeks of age. Treat broiler chicks at 4 and 7 weeks of age.

Swine

For each 100 lb. (45 kg) of herd weight: Give ½ fluid ounce (15 ml) of Wazine-34 per U.S. gallon (3.8 liters) of drinking water. Treat sows and gilts before breeding and up to 2 weeks before farrowing: treat boars at any time; and treat pigs 1 week after weaning and every 30 days thereafter.

For use in automatic water proportioners: Mix 1 part Wazine-34 with 1 part water and set proportioner to deliver 1 fluid ounce (30 ml) per gallon of drinking water and give for 1 day.

Caution: Do not give to sick, feverish, underweight, or physically weak birds or animals.

WARNING: Withdraw medication prior to slaughter as follows:

Chickens - 14 days
Turkeys - 14 days
Swine - 21 days

Do not use in chickens producing eggs for human consumption.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Store above 32°F (0°C).
FLEMING LABORATORIES, INC.
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