

ZOASHIELD- dinitolmide granule
Elanco US Inc.

Elanco™

ZoaShield™ 25%™

Net wt. 50 LB (22.68 kg)

(zoalene Type A medicated article)

Coccidiostat

Active Drug Ingredient

Zoalene (3,5-dinitro-o-toluamide) 25%

Inactive Ingredients

Roughage product, calcium carbonate, mineral oil 75%

For use in preparation of feeds for chickens and turkeys only. Livestock remedy.

Indications

Broiler Chickens: For prevention and control of coccidiosis.

Replacement Chickens: For development of active immunity to coccidiosis.

Growing Turkeys: For prevention and control of coccidiosis.

Directions

It is suggested that a mixture of ZoaShield 25% and some feed ingredient be prepared prior to mixing in with the finished ration. This will ensure thorough and even distribution in the feed.

For chickens grown for meat purposes:

Use 1 lb (454 g) of ZoaShield 25% per 2,000 lb (909 kg) of finished product to produce a feed containing 0.0125% zoalene. ZoaShield 25% should be thoroughly blended into the finished feed. Feed containing zoalene should be fed continuously as the only ration from the time chicks are placed in floor pens until they are slaughtered for meat.

For replacement chickens:

Feed containing zoalene can be used in a program to raise replacement birds. When used under conditions of exposure to coccidiosis, it will allow immunity to develop adequately to protect against losses due to the disease when the birds are placed on nonmedicated feed for egg laying purposes. The following chart outlines the type of

feeding program to follow where complete formulated feed is the sole ration:

Growing condition	Starter ration			Grower ration*		
	% Zoalene per ton	ZoaShield 25% to be added per ton of feed		% Zoalene in feed	ZoaShield 25% to be added per ton of feed	
		(lb)	(g)		(lb)	(g)
Severe exposure to coccidiosis expected	0.0125	1	454	0.0083 to 0.0125	2/3 to 1	303 to 454
Light to moderate exposure to coccidiosis expected	0.0083 to 0.0125	2/3 to 1	303 to 454	0.004 to 0.0083	1/3 to 2/3	151 to 303

*Grower ration not to be fed to birds over 14 weeks of age.

For turkeys grown for meat purposes only:

When turkey poults are reared in confinement and severe exposure to coccidiosis is usually a problem, use 1½ lb (681 g) of ZoaShield 25% per ton (2,000 lb) of feed to produce a finished feed containing 0.0187% zoalene. Under the usual conditions of rearing turkey poults, or when turkey poults are on range, use 1 lb (454 g) of ZoaShield 25% per 2,000 lb (909 kg) of feed to produce a finished feed containing 0.0125% zoalene. The feed containing zoalene should be fed continuously until the birds are 14 to 16 weeks of age.

Combinations with other drugs

Use only in accordance with the current New Animal Drug Regulation for zoalene, Section 558.680 of the Regulations promulgated under the Federal Food, Drug and Cosmetic Act.

Cautions

Not to be fed to laying birds.

Consult a veterinarian or poultry pathologist if losses exceed 0.5% in a two-day period.

Avoid inhaling dust.

Avoid contact with eyes.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Elanco, 1-800-428-4441. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

Store at or below 25°C. Excursions permitted to 40°C.

Restricted Drug (California) - use only as directed. Not for human use.

Approved by FDA under ANADA # 200-690

ZoaShield, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140, USA

YL103082X

Principal Display Panel - 50 lb Bag Label

Elanco[™]

ZoaShield[™] 25%

[™]

Net wt. 50 LB (22.68 kg)

(zoalene Type A medicated article)

Coccidiostat

Elanco™

ZoaShield™ 25%

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For replacement chickens:

Feed containing zoalene can be used in a program to raise replacement birds. When used under conditions of exposure to coccidiosis, it will allow immunity to develop adequately to protect against losses due to the disease when the birds are placed on unmedicated feed for egg laying purposes. The following chart outlines the type of feeding program to follow where complete formulated feed is the sole ration:

Growing condition	% Zoalene per ton	Starter ration		Grower ration*		
		ZoaShield 25% to be added per ton of feed		% Zoalene in feed	ZoaShield 25% to be added per ton of feed	
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				to	to	
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	to	to	to	to	to	to
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Manufactured for:

Elanco US Inc.

Greenfield, IN 46140, USA

YL103082X

ZOASHIELD

dinitolmide granule

Product Information

Product Type	OTC TYPE A MEDICATED ARTICLE ANIMAL DRUG	Item Code (Source)	NDC:58198-7636
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DINITOLMIDE (UNII: AOX68RY4TV) (DINITOLMIDE - UNII:AOX68RY4TV)	DINITOLMIDE	5.67 kg in 22.68 kg

Inactive Ingredients

Ingredient Name	Strength
Calcium Carbonate (UNII: H0G9379FGK)	
Mineral Oil (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-7636-1	22.68 kg in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200690	09/18/2020	

Labeler - Elanco US Inc. (966985624)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Rongyao Biotech Co., Ltd.		529047233	API MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Pharmgate Inc.		079628468	MANUFACTURE, PACK, LABEL

Revised: 1/2021

Elanco US Inc.