ROFENAID 40- sulfadimethoxine and ormetoprim powder Zoetis Inc.

RofenAid 40

DESCRIPTION

RofenAid

40

Sulfadimethoxine & Ormetoprim

Type A Medicated Article

Antibacterial

Anticoccidial

For use in broiler, replacement (breeder and layer) chickens, turkeys, ducks and chukar partridges only.

Active Drug Ingredients

Sulfadimethoxine	\dots 113.5 grams per pound (25%),
Ormetoprim	68.1 grams per pound (15%)
in a carrier suitable for incorporation in feed.	

For use in manufacturing medicated feeds only

Chickens

Broiler and replacement (breeder and layer) chickens

Indications:

As an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti* and *E. mivati*; as an aid in the prevention of bacterial infections caused by *Haemophilus gallinarum* (infectious coryza), *Escherichia coli* (colibacillosis) and *Pasteurella multocida* (fowl cholera).

Use directions:

Add 1 lb of RofenAid 40 to one ton of feed to provide 0.02% (113.5 g/ton [0.0125%] sulfadimethoxine and 68.1 g/ton [0.0075%] ormetoprim) concentration in feed. Feed continuously as the sole ration.

Warning:

Do not feed to chickens over 16 weeks (112 days) of age.

Turkeys

Indications:

As an aid in the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. gallopavonis*, and *E. meleagrimitis*; for the prevention of bacterial infections caused by *Pasteurella multocida* (fowl cholera).

Use directions:

Add 1/2 lb of RofenAid 40 to one ton of feed to provide 0.01% (56.75 g/ton [0.00625%] sulfadimethoxine and 34.05 g/ton [0.00375%] ormetoprim) concentration in feed. Feed continuously as

the sole ration.

Ducks

Ducks, including breeding ducks

Indications:

As an aid in the control of bacterial infections due to *Pasteurella multocida* (fowl cholera) in ducks including breeding ducks.

Use directions:

Add 2 lbs of RofenAid 40 to one ton of feed to provide 0.04% (227 g/ton [0.025%] sulfadimethoxine and 136.2 g/ton [0.015%] ormetoprim) concentration in feed. Medication should be started at the first signs of infection. Feed for 7 days as the sole ration.

Ducks

Indications:

As an aid in the control of bacterial infections due to *Escherichia coli*, *Riemerella anatipestifer* (strains 2, 3 & 4) and severe challenge of *P. multocida* (fowl cholera).

Use directions:

Add 4 lbs of RofenAid 40 to one ton of feed to provide 0.08% (454 g/ton [0.050%] sulfadimethoxine and 272.4 g/ton [0.030%] ormetoprim) concentration in feed. Medication should be started at the first signs of infection. Feed for 7 days as the sole ration.

Caution:

Not for breeding ducks. The safety of feeding sulfadimethoxine and ormetoprim at levels higher than 0.025% and 0.015%, respectively, in breeding ducks has not been established.

Chukar Partridges

Indications:

For the prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis*.

Use directions:

Add 1 lb of RofenAid 40 to one ton of feed to provide 0.02% (113.5 g/ton [0.0125%] sulfadimethoxine and 68.1 g/ton [0.0075%] ormetoprim) concentration in feed. Feed continuously as the sole ration to young birds up to 8 weeks of age.

Caution:

The safety of feeding RofenAid 40 to breeding stock has not been established.

Warning

Do not feed to turkeys and ducks producing eggs for food. Withdraw 5 days prior to slaughter of broiler and replacement chickens, turkeys and ducks.

Note

Manufacture of Type B or C feeds from this product requires a Medicated Feed Mill License.

Labels for feeds containing RofenAid 40 must contain appropriate indications, limitations and warnings as well as required feed ingredient information.

Restricted Drug (California) - Use only as directed. Not for human use. Approved by FDA under NADA # 040-209 Store below 25°C (77°F), excursions permitted to 37°C (99°F).

zoetis

Distributed by: Zoetis Inc. Kalamazoo, MI 49007

Product of China

10010602

PRINCIPAL DISPLAY PANEL



Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

Sulfadimethoxine & Ormetoprim Type A Medicated Article

> Antibacterial Anticoccidial

Net wt 50 LB (22.68 kg)

zoetis

sulfadimethoxine and ormetoprim powder

Product Information			
Product Type	VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG	Item Code (Source)	NDC:54771- 1446
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SULFADIMETHO XINE (UNII: 30 CPC5LDEX) (SULFADIMETHO XINE - UNII:30 CPC5LDEX)	SULFADIMETHOXINE	113.5 g in 0.45 kg	
ORMETOPRIM (UNII: M3EFS94984) (ORMETOPRIM - UNII:M3EFS94984)	ORMETOPRIM	68.1 g in 0.45 kg	

Product Characteristics		
Color	BROWN (beige to light tan)	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-1446-0	22.68 kg in 1 BAG		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA040209	12/0 1/20 18	

Labeler - Zoetis Inc. (828851555)

Establishment			
Name	Address	ID/FEI	Business Operations
Zoetis LLC		069370112	MANUFACTURE

Revised: 4/2020 Zoetis Inc.