

ALBON BOLUS- sulfadimethoxine tablet
Zoetis Inc.

ALBON®
(sulfadimethoxine)

Boluses

DESCRIPTION: Albon is a low-dose, rapidly absorbed, long-acting sulfonamide.

Actions: Sulfadimethoxine has been demonstrated in laboratory studies to be effective against a wide variety of organisms, such as streptococci, staphylococci, and members of the *E. coli*-salmonella group of bacteria.

Comparatively low doses of Albon give rapid, sustained blood levels required for effective disease therapy.

INDICATIONS AND USAGE: Albon is effective in the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine in cattle.

WARNINGS:

Not for Human Use

Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food.

Do not slaughter animals for food purposes within 7 days following the last treatment.

A withdrawal period has not been established for this product in preruminating calves.

Do Not Use in Calves to be Processed for Veal



PRECAUTIONS: During treatment period, make certain that animals maintain adequate water intake.

If animals show no improvement within 2–3 days, reevaluate your diagnosis. Treatment should not be continued beyond 5 days.

DOSAGE AND ADMINISTRATION: Albon should be administered to cattle so that the initial dose is equivalent to 25 mg/lb of body weight and each subsequent daily dose is equivalent to 12.5 mg/lb of body weight. Length of treatment will depend on clinical response. In most cases, treatment for 3–4 days is adequate. Treatment should not be continued beyond 5 days.

The following tables show the dosage and dosage forms to be used for cattle of different weights.

Albon Boluses, 5 g

Dosage Schedule for Cattle: 200–600 lb of body weight

Animal	First Day	Daily for the
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Weight, lb	First Day	Following 3–4 Days
200	1 bolus	1/2 bolus
300	1 1/2 boluses	1 bolus
400	2 boluses	1 bolus
500	2 1/2 boluses	1 1/2 boluses
600	3 boluses	1 1/2 boluses

Albon Boluses, 15 g

Dosage Schedule for Cattle: 600–1,200 lb of body weight

Animal Weight, lb	First Day	Daily for the Following 3–4 Days
600	1 bolus	1/2 bolus
800	1 1/2 boluses	1 bolus
1,000-1,200	2 boluses	1 bolus

TOXICITY AND SAFETY: Albon has been shown to be a well-tolerated sulfonamide with relatively high solubility at the pH normally occurring in the kidney and with a low degree of toxicity. Following the administration of Albon at the recommended dosage, no undesirable side effects have been observed.

Store at Controlled Room Temperature 15°–30°C (59°–86°F)

HOW SUPPLIED: Albon Boluses are supplied in the following dosage forms:

5 g sulfadimethoxine per single-scored bolus

15 g sulfadimethoxine per single-scored bolus

Restricted Drug (California)—Use Only as Directed

NADA #31-715, Approved by FDA

Distributed by:

Zoetis Inc.

Kalamazoo, MI 49007

13904000

Revised: January 2013

PRINCIPAL DISPLAY PANEL - 5 g - 50 Bolus Bottle Label

ALBON®

(sulfadimethoxine)

Each bolus contains 5 g sulfadimethoxine.

Not for Human Use

For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine in cattle.

Bolus

5 g

50 boluses

NADA #31-715, Approved by FDA

zoetis

ALBON[®]
(sulfadimethoxine)

Each bolus contains 5 g sulfadimethoxine.

Not for Human Use

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Bolus 5 g

50 boluses

NADA #31-715, Approved by FDA

zoetis

Warnings: Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Do not slaughter animals for food purposes within 7 days following the last treatment. A withdrawal period has not been established for this product in pre-ruminating calves. Do Not Use in Calves to be Processed for Veal. Store at Controlled Room Temperature 15°–30°C (59°–86°F). Restricted Drug (California)—Use Only as Directed

DISCARD MILK FOR
60 HOURS
AFTER LAST TREATMENT

DO NOT SLAUGHTER COW FOR
7 DAYS
AFTER LAST TREATMENT

TAKE TIME
OBSERVE
LABEL
DIRECTIONS

Dosage and Administration: Animals should receive an initial dose of 25 mg/kg of body weight followed by subsequent daily doses of 12.5 mg/kg of body weight. If animals show no improvement within 2 or 3 days, reevaluate diagnosis. Treatment should not be continued beyond 5 days.

Animal Weight, lb	First Day	Daily for the Following 3 or 4 Days
200	1 bolus	1/2 bolus
300	1 1/2 boluses	1 bolus
400	2 boluses	1 bolus
500	2 1/2 boluses	1 1/2 boluses
600	3 boluses	1 1/2 boluses

For detailed dosage recommendations, indications, limitations, and precautions, see additional product information attached.
Caution: During treatment period, make certain that animals maintain a adequate water intake.

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

LOT
EXP

13904300
8448000

0 8721901817 0

FP0 - UPC @ 90%

PRINCIPAL DISPLAY PANEL - 15 g - 12 Bolus Bottle Label

ALBON[®]

(sulfadimethoxine)

Each bolus contains 15 g sulfadimethoxine.

Not for Human Use

For the treatment of shipping fever complex and bacterial pneumonia associated with organisms such as *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine in cattle.

Bolus

15 g

12 boluses

NADA #31-715, Approved by FDA

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ALBON®
(sulfadimethoxine)

Each bolus contains 15 g sulfadimethoxine.

Not for Human Use

For the treatment of shipping fever complex and bacterial pneumonia associated with organisms such as *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine in cattle.

Bolus 15 g
12 boluses
NADA #31-715, Approved by FDA

Warnings: Milk taken from animals during treatment and for 48 hours (5 milkings) after the last treatment must not be used for food.
Do not slaughter animals for food purposes within 7 days following the last treatment.
A withdrawal period has not been established for use in pregnant cows.
Do Not Use in Cattle to be Processed for Veal
Store at Control Room Temperature 15°-30°C (59°-86°F)
Restricted Drug (California)—Use Only as Directed

THE TMR
DIRECTION

DISCARD MILK FOR 60 HOURS AFTER LAST TREATMENT
DO NOT SLAUGHTER COW FOR 7 DAYS AFTER LAST TREATMENT

Animal Weight, lb
500 800 1,000-1,200
First Day 1 bolus 1 1/2 boluses 2 boluses

Daily for the Following 3 or 4 Days
500-800 1 bolus 1 1/2 boluses 1 bolus
800-1,000 1 1/2 boluses 1 bolus 1 bolus

Caution: During treatment period, make certain that animals maintain adequate water intake.

zoetis
One North Star Drive
Kalamazoo, MI 49001

13904100
LOT
EXP
IMPRINT AREA
8449000

0 87219 01819 4

PRINCIPAL DISPLAY PANEL - 15 g - 50 Bolus Bottle Label

ALBON® (sulfadimethoxine)

Each bolus contains 15 g sulfadimethoxine.

Not for Human Use

For the treatment of shipping fever complex and bacterial pneumonia associated with organisms such as *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine in cattle.

Bolus

15 g

50 boluses

NADA #31-715, Approved by FDA

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ALBON®
(sulfadimethoxine)

Each bolus contains 15 g sulfadimethoxine.

Not for Human Use

For the treatment of shipping fever complex and bacterial pneumonia associated with organisms such as *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine in cattle.

Bolus 15 g
50 boluses
NADA #31-715, Approved by FDA

Warnings: Milk taken from a animal's during treatment and for 48 hours (5 milkings) after the last treatment must not be used for food.
Do not slaughter animals for food purposes within 7 days following the last treatment.
A withdrawal period has not been established for this product in pregnant cows.
Do Not Use in Cattle to be Processed for Veal
Store at Control Room Temperature 15°-30°C (59°-86°F)
Restricted Drug (California)—Use Only as Directed

THE TMR
DIRECTION

DISCARD MILK FOR 60 HOURS AFTER LAST TREATMENT
DO NOT SLAUGHTER COW FOR 7 DAYS AFTER LAST TREATMENT

Animal Weight, lb
600 800 1,000-1,200
First Day 1 bolus 1 1/2 boluses 2 boluses

Daily for the Following 3 or 4 Days
600 1 bolus 1 1/2 boluses 1 bolus
800 1 1/2 boluses 1 bolus 1 bolus

Caution: During the treatment period, make certain that animals maintain adequate water intake.

zoetis
One North Star Drive
Kalamazoo, MI 49001

13904100
LOT
EXP
IMPRINT AREA
8450000

0 87219 01821 7

ALBON BOLUS

sulfadimethoxine tablet

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:54771-8449
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
sulfadimethoxine (UNII: 30CPC5LDEX) (sulfadimethoxine - UNII:30CPC5LDEX)	sulfadimethoxine	5 g

Product Characteristics

Color	WHITE (White to Off White)	Score	2 pieces
Shape	OVAL (Oblong, biconvex bolus)	Size	35mm
Flavor		Imprint Code	Albon;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-8449-1	50 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA031715	04/12/1968	

ALBON BOLUS

sulfadimethoxine tablet

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:54771-8450
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
sulfadimethoxine (UNII: 30CPC5LDEX) (sulfadimethoxine - UNII:30CPC5LDEX)	sulfadimethoxine	15 g

Product Characteristics

Color	WHITE (White to Off White)	Score	2 pieces
Shape	OVAL (Oblong, biconvex bolus)	Size	53mm

Flavor		Imprint Code	Albon;15
Contains			
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:54771-8450-1	12 in 1 BOTTLE, PLASTIC	
2	NDC:54771-8450-2	50 in 1 BOTTLE, PLASTIC	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA031715	04/12/1968	

Labeler - Zoetis Inc. (828851555)

Establishment			
Name	Address	ID/FEI	Business Operations
Zoetis LLC		039055157	MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
SHANGHAI ZHONGXI SUNVE PHARMACEUTICAL CO., LTD.		544646342	API MANUFACTURE