SUSTAIN III CALF- sulfamethazine sustained release calf tablet, extended release
Bimeda, Inc.

Sustain III® Calf Bolus(sulfamethazine)

SUSTAINED RELEASED BOLUS (72 HOURS) Antibacterial

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

NOT FOR HUMAN USE

KEEP OUT OF REACH OF CHILDREN

Approved by FDA under NADA # 120-615

EACH BOLUS CONTAINS: Sulfamethazine (formulated in a sustained release base), 123.8 grains (8.02 grams).

Sustain III Calf Boluses (sulfamethazine) are intended for oral administration to ruminating replacement calves (calves over one (1) month old that are not on an all-milk diet).

Sustain III Calf Boluses are indicated for the treatment of the following diseases when caused by one or more of the following pathogenic organisms sensitive to sulfamethazine: Bacterial Pneumonia (*Pasteurella* spp.), Colibacillosis (Bacterial Scours) (*E. coli*) and Calf Diphtheria (*Fusobacteriulm necrophorum*).

RESIDUE WARNING: Treated animals intended for human consumption should not be slaughtered for food for at least 12 days after the last dose. Exceeding two (2) consecutive doses may cause violative tissue residues to remain beyond the withdrawal time. Do not use in calves under one (1) month of age or calves being fed an all-milk diet. Use in these classes of calves may cause violative residues to remain beyond the withdrawal time. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues.

CAUTION: This drug, like all sulfonamides, may cause toxic reactions and irreparable injury unless administered with adequate and continuous supervision. **Follow recommended dosages carefully.** Fluid intake must be adequate at all times throughout the three-day therapy provided by the sustained release bolus. This product has not been shown to be effective for non-ruminating calves.

CONTACT INFORMATION: To report adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

DOSAGE AND ADMINISTRATION: Sustain III Calf Boluses (sulfamethazine) are designed to be administered orally to ruminating replacement calves (**See RESIDUE WARNING Statemen**t). Sustain II Calf Boluses should be given according to the following dosage schedule.

No. of Boluses	2	3	4	5	6
Animal Body Weight (lbs)	100	150	200	250	300

This bolus may be divided for better approximation of the correct dose; however, care should be taken not to crush the bolus. Care should also be taken to ensure the entire dose has been swallowed by the animal. Observe animals following the administration to ensure boluses are not regurgitated. Lubricate bolus before dosing animals.

Sustain III Calf Boluses are designed to provide a therapeutic sulfamethazine level in approximately 6 hours, and persist in providing this level for 72 hours (3 days). After 72 hours, all animals should be re-examined for persistence of observable disease signs. If signs are present, consult a veterinarian. It is strongly recommended that a second dose be given to provide an additional 72 hours of therapy, particularly in those more severe cases. The above schedule should be used at each 72-hour interval.

Store at 20°C - 25°C (68°F - 77°F), with excursions permitted to 15°C - 30°C (59°F - 86°F).

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Sustain III Calf Boluses (sulfamethazine) are intended for oral administration to ruminating replacement calves (calves over one (1) month old that are not on an all-milk diet). Sustain III Calf Boluses are indicated for the treatment of the following diseases when caused by one or more of the following pathogenic organisms sensitive to sulfamethazine: Bacterial Pneumonia (*Pasteurella* spp.), Colibacillosis (Bacterial Scours) (*E. coli*) and Calf Diphtheria (*Fusobacterium necrophorum*).

RESIDUE WARNING: Treated animals intended for human consumption should not be slaughtered for food for at least 12 days after the last dose. Exceeding two (2) consecutive doses may cause violative tissue residues to remain beyond the withdrawal time. Do not use in calves under one (1) month of age or calves being fed an all-milk diet. Use in these classes of calves may cause violative residues to remain beyond the withdrawal time. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues.

CAUTION: This drug, like all sulfonamides, may cause toxic reactions and irreparable injury unless administered with adequate and continuous supervision. **Follow recommended dosages carefully.** Fluid intake must be adequate at all times throughout the three-day therapy provided by the sustained release bolus. This product has not been shown to be effective for non-ruminating calves.

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Antibacterial

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Net Contents:
25 Boluses

Manufactured by:
Bimeda, Inc.
Le Sueur, MN 56058
www.bimeda.com

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Sustain III® is a Registered Trademark of Bimeda, Inc.

LOT:
EXP:

SUSTAIN III CALF
sulfamethazine sustained release calf tablet, extended release

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:61133-1333
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sulfamethazine (UNII: 48U51W007F) (SULFAMETHAZINE - UNII:48U51W007F)	Sulfamethazine	8.02 g in 8.63 g

Product Characteristics

Color	blue	**Score**	2 pieces
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	NA
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61133-1333-1	215.75 g in 1 BOTTLE		
2	NDC:61133-1333-2	431.5 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA120615	07/18/1984	

Labeler - Bimeda, Inc. (060492923)

Registrant - Bimeda, Inc. (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda, Inc.		060492923	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Second Pharma Company, Ltd.		527973171	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Nanhai Beisha Pharmaceutical Co.		527929800	api manufacture

Revised: 3/2024   Bimeda, Inc.