BO-SE- sodium selenite and .alpha.-tocopherol acetate, d- injection, solution
Merck Sharp & Dohme Corp.

BO-SE®
(SELENIUM, VITAMIN E)
Injection

FOR VETERINARY USE ONLY

PRODUCT
INFORMATION

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

DESCRIPTION BO-SE (selenium, vitamin E) is an emulsion of selenium-tocopherol for the prevention and treatment of white muscle disease (Selenium-Tocopherol Deficiency) syndrome in calves, lambs, and ewes, and as an aid in the prevention and treatment of Selenium-Tocopherol Deficiency in sows and weanling pigs. **Each mL contains**: 2.19 mg sodium selenite (equivalent to 1 mg selenium), 50 mg (68 USP units) vitamin E (as *d*-alpha tocopheryl acetate), 250 mg polysorbate 80, 2% benzyl alcohol (preservative), water for injection q.s. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

PHARMACOLOGY It has been demonstrated that selenium and tocopherol exert physiological effects and that these effects are intertwined with sulfur metabolism. Additionally, tocopherol appears to have a significant role in the oxidation process, thus suggesting an interrelationship between selenium and tocopherol in overcoming sulfur induced depletion and restoring normal metabolism. Although oral ingestion of adequate amounts of selenium and tocopherol would seemingly restore normal metabolism, it is apparent that the presence of sulfur and, perhaps, other factors interfere during the digestive processwith proper utilization of selenium and tocopherol. When selenium and tocopherol are injected, they bypass the digestive process and exert their full metabolic effects promptly on cell metabolism. Anti-inflammatory action has been demonstrated by selenium-tocopherol in the Selye Pouch Technique and experimentally induced polyarthritis study in rats.

INDICATIONS BO-SE (selenium, vitamin E) is recommended for the prevention and treatment of white muscle disease (Selenium-Tocopherol Deficiency) syndrome in calves, lambs, and ewes. Clinical signs are: stiffness and lameness, diarrhea and unthriftiness, pulmonary distress and/or cardiac arrest. In sows and weanling pigs, as an aid in the prevention and treatment of diseases associated with Selenium-Toco pherol deficiency, such as hepatic necrosis, mulberry heart disease, and white muscle disease. Where known deficiencies of selenium and/or vitamin E exist, it is advisable, from the prevention and control standpoint, to inject the sow during the last week of pregnancy.

CONTRAINDICATIONS DO NOT USE IN PREGNANT EWES. Deaths and abortions have been reported in pregnant ewes injected with this product.

WARNINGS Anaphylactoid reactions, some of which have been fatal, have been reported in animals administered BO-SE Injection. Signs include excitement, sweating, trembling, ataxia, respiratory distress, and cardiac dysfunction. Selenium- Vitamin E

preparations can be toxic when improperly administered.

Residue Warnings: Discontinue use 30 days before the treated calves are slaughtered for human consumption. Discontinue use 14 days before the treated lambs, ewes, sows, and pigs are slaughtered for human consumption.

PRECAUTIONS Selenium-Tocopherol Deficiency (STD) syndrome produces a variety and complexity of symptoms often interfering with a proper diagnosis. Even in selenium deficient areas there are other disease conditions which produce similar clinical signs. It is imperative that all these conditions be carefully considered prior to treatment of STD syndrome. Serum selenium levels, elevated SGOT, and creatine levels may serve as aids in arriving at a diagnosis of STD, when associated with other indices. Selenium is toxic if administered in excess. A fixed dose schedule is therefore important (read package insert for each selenium-tocopherol product carefully before using).

ADVERSE REACTIONS Reactions, including acute respiratory distress, frothing from the nose and mouth, bloating, severe depression, abortions, and deaths have occurred in pregnant ewes. Do not use product with phase separation or turbidity.

DOSAGE AND ADMINISTRATION Inject subcutaneously or intramuscularly. Calves: 2.5-3.75 mL per 100 pounds of body weight depending on the severity of the condition and the geographical area. Lambs 2 weeks of age and older: 1 mL per 40 pounds of body weight (minimum, 1 mL). Ewes: 2.5 mL per 100 pounds of body weight. Sows: 1 mL per 40 pounds of body weight. Weanling pigs: 1 mL per 40 pounds of body weight (minimum, 1 mL). Not for use in newborn pigs.

Store at 25°C (77°F) with excursions permitted between 23 - 32°C (74 - 89°F).

Use within 90 days of first puncture and puncture a maximum of 12 times. If more than 12 punctures are anticipated, the use of multi-dosing equipment is recommended. When using a draw-off spike or needle with bore diameter larger than 16G, discard any product remaining in the vial immediately after use.

Occasionally, the product may segregate in two phases or may become turbid. Do not use product that has exhibited phase separation or turbidity.

HOW SUPPLIED 100 mL sterile, multiple dose vial, NDC 0061-0807-05.

Approved by FDA under NADA # 012-635

Made in Germany.
Rev. 12/20

MERCK
Animal Health

385824 R2

PRINCIPAL DISPLAY PANEL - 100 mL Vial Carton

100 mL Sterile

1 mg/mL

SELENIUM

NDC 0061-0807-05

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(SELENIUM, VITAMIN E)

Injection
Veterinary

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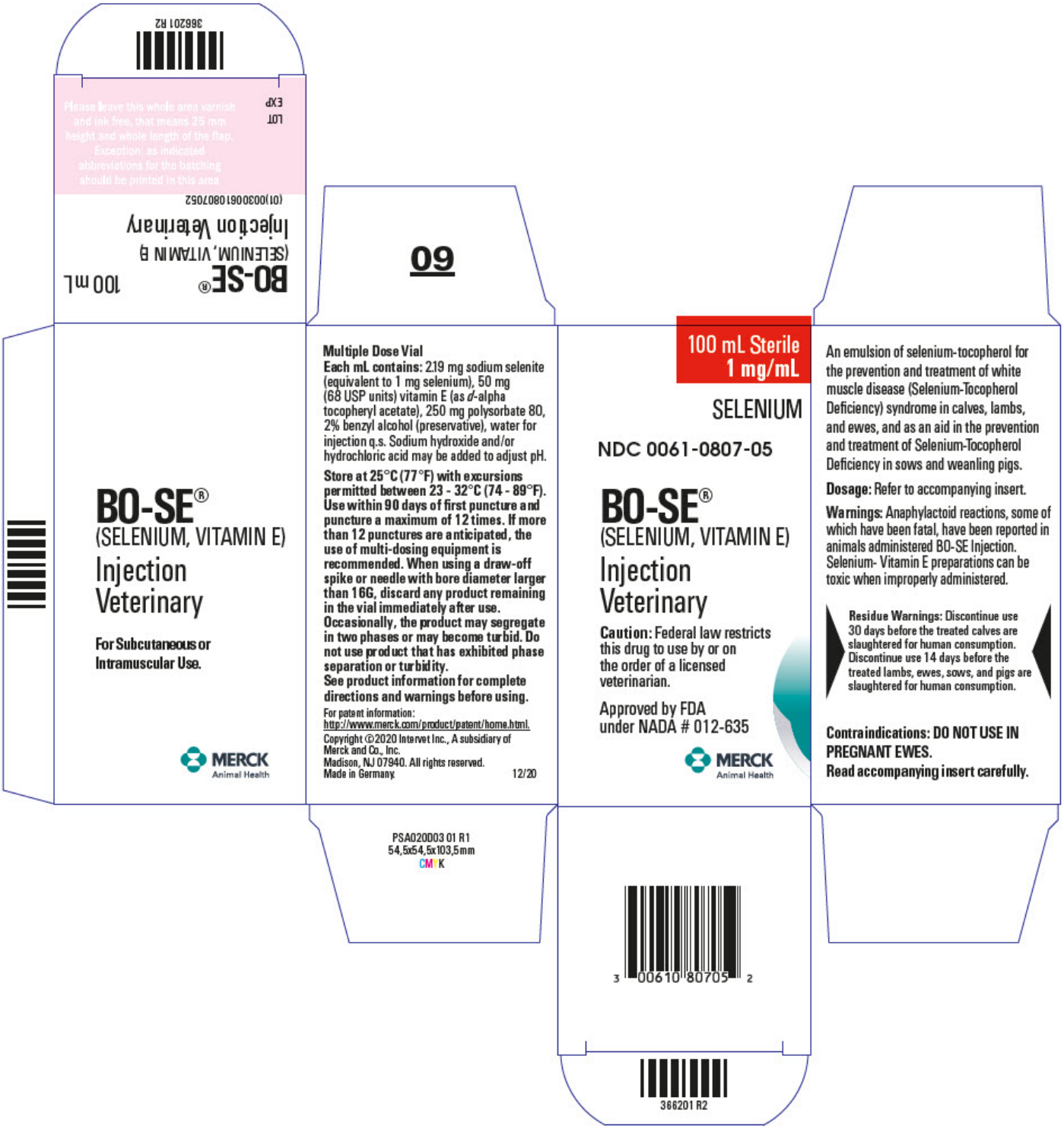
Animal Health



BO-SE

sodium selenite and .alpha.-tocopherol acetate, d- injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:0061-0807
Route of Administration	SUBCUTANEOUS, INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM SELENITE (UNII: HIW548RQ3W) (SELENITE ION - UNII:KXO0259XJ1)	SELENIUM	1 mg in 1 mL
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	68 [USP'U] in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0061-0807-05	1 in 1 CARTON		
1		100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA012635	07/09/1964	

Labeler - Merck Sharp & Dohme Corp. (001317601)

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