

POSILAC®

(sterile somatotribove zinc suspension)

Description: POSILAC (sterile somatotribove zinc suspension) is a sterile, prolonged-release injectable formulation of a recombinant DNA-derived bovine somatotropin analogue in single-dose syringes each containing 500 mg of somatotribove zinc.

Indications For Use: POSILAC is for use in healthy lactating dairy cows to increase production of marketable milk.

Dosage: Inject one syringe of POSILAC every 14 days beginning during the 9th week after calving and continuing until the end of lactation.

Administration: Allow syringes to warm to room temperature (15° to 30°C; 59° to 86°F) before use.

Inject POSILAC subcutaneously (under the skin) in the postscapular region (behind the shoulder) or in the depression on either side of the tailhead (see diagrams below). The injection site should be free of surface debris. Attach a needle securely to a syringe and inject entire contents subcutaneously. Do not reuse needles or syringes.

Tailhead Depression



Inject straight into tailhead depression.

Behind the Shoulder



Gather skin and inject between skin and muscle layers.

Human Warnings: Avoid prolonged or repeated contact of POSILAC with eyes and skin. POSILAC is a protein. Frequent skin contact with proteins in general may produce an allergic skin reaction in some people. Always wash hands and skin exposed to POSILAC with soap and water after handling. Clothing soiled with the product should be laundered before reuse.

Not for human use.

Keep out of reach of children.

Precautions and Side Effects:

Use in lactating dairy cattle only.

Safety to replacement bulls from dairy cows injected with POSILAC has not been established.

To minimize injection site blemishes on the carcass at time of slaughter, avoid injections of POSILAC within 2 weeks of expected slaughter.

Nutritional Management: Feed intake increases over several weeks after initiating the use of POSILAC. This increase occurs earlier for first calf heifers than for second lactation or older cows. Use of POSILAC may reduce the amount of body condition that is normally regained during lactation. This effect is more pronounced for second lactation or older cows. Voluntary feed intake may be increased and body condition decreased during both the dry period and subsequent early lactation.

Cows should be fed diets formulated to meet or exceed the nutritional requirements recommended by the National Research Council. Milk yield, stage of lactation, and body condition should be considered when making dietary changes. The feeding program should be managed to optimize energy intake and to have cows in appropriate body condition particularly during late lactation and the dry period.

Reproduction: Use of POSILAC (sterile somatotribove zinc suspension) may result in reduced pregnancy rates in injected cows and an increase in days open for first calf heifers. Use of POSILAC has also been associated with increases in cystic ovaries and disorders of the uterus during the treatment period. Cows injected with POSILAC may have small decreases in gestation length and birth weight of calves and they may have increased twinning rates. Also, the incidence of retained placenta may be higher following subsequent calving. Use of POSILAC should be preceded by implementation of a comprehensive and ongoing herd reproductive health program.

Mastitis: Cows injected with POSILAC are at an increased risk for clinical mastitis (visibly abnormal milk). The number of cows affected with clinical mastitis and the number of cases per cow may increase. In addition, the risk of subclinical mastitis (milk not visibly abnormal) is increased. In some herds, use of POSILAC has been associated with increases in somatic cell counts. Mastitis management practices should be thoroughly evaluated prior to initiating use of POSILAC.

General Health: Use of POSILAC is associated with increased frequency of use of medication in cows for mastitis and other health problems.

Cows injected with POSILAC may experience periods of increased body temperature unrelated to illness. To minimize this effect, take appropriate measures during periods of high environmental temperature to reduce heat stress. Care should be taken to differentiate increased body temperature due to use of POSILAC from an increased body temperature that may occur due to illness.

Use of POSILAC may result in an increase in digestive disorders such as indigestion, bloat, and diarrhea.

There may be an increase in the number of cows experiencing periods of "off-feed" (reduced feed intake) during use of POSILAC.

Studies indicated that cows injected with POSILAC had increased numbers of enlarged hocks and lesions (e.g., lacerations, enlargements, calluses) of the knee (carpal region), and second lactation or older cows had more disorders of the foot region. However, results of these studies did not indicate that use of POSILAC increased lameness.

Injection Site Reactions: A mild transient swelling of 3-5 cm (1-2 inches) in diameter may occur at the injection site beginning about 3 days after injection and may persist up to 6 weeks following injection. Some cows may experience swellings up to 10 cm (4 inches) in diameter that remain permanent but are not associated with animal health problems. However, if permanent blemishes are objectionable to the user, administration of the product to the particular animal should be discontinued. Use of POSILAC in cows in which injection site swellings repeatedly open and drain should be discontinued.

Additional Veterinary Information: Care should be taken to differentiate increased body temperature due to use of POSILAC from an increased body temperature that may occur due to illness.

Use of POSILAC has been associated with reductions in hemoglobin and hematocrit values during treatment.

Additional Information: Milk production response during each 14-day injection period is cyclic and will be greatest during the middle of each period.

No milk discard or preslaughter withdrawal period is required.

Storage: Store under refrigeration (2° to 8°C; 36° to 46°F). DO NOT FREEZE. Avoid prolonged exposure to excessively high temperature and sunlight to prevent a decrease in product activity. Expiration dates are stated on syringe and carton labeling.

Environmental Safety: Used syringes and needles should be placed in a leak-resistant puncture-resistant container for disposal in accordance with applicable Federal, state and local regulations.

How Supplied: Single-dose syringes in 25-pack cartons.

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