

Microencapsulated Estradiol Benzoate  
Suspension Implant  
For Suckling Beef Calves  
Manufactured by a non-sterilizing process

**Celerin™ C**



This package consists of two vials, one vial containing 50 doses of estradiol benzoate microspheres and one vial containing 50mL of diluent.

For Use in Animals Only

**Description:**

**Celerin™ C** (estradiol benzoate) contains 10mg estradiol benzoate per dose in Theraphase™ microspheres. The microspheres have been designed to release estradiol benzoate at a controlled rate to increase rate of weight gain.



Manufactured by  
PR Pharmaceuticals, Inc.  
1716 Heath Parkway  
Fort Collins, Colorado 80524

65-20505/00/0603

NADA 141-041, Approved by FDA

Read enclosed package insert and use as directed.  
Store under refrigerated temperatures between 36° and 46°F (2° and 8°C).

Avoid heat and direct sunlight.

Exposure to excessive heat and direct sunlight will damage product integrity.

Lot No.:

Exp. Date:

Patent No's: US 5,288,496 US 5,401,507 US 5,427,796

NDC XXXXXXXXXX



**Celerin™ C**

**(estradiol benzoate)**  
**Microencapsulated Estradiol Benzoate  
Suspension Implant  
For Suckling Beef Calves**  
Manufactured by a non-sterilizing process

After mixing, **Celerin™ C** suspension is ready to administer.  
This powder will provide a suspension of Theraphase™ microspheres containing 10mg/mL estradiol benzoate.

Contains 500mg estradiol benzoate (50-10mg doses).  
**NET WEIGHT 2.5 GRAMS**  
16-00010

**Indications:** **Celerin™ C** (estradiol benzoate) is indicated for increased rate of weight gain in suckling beef calves.

Do not use in veal calves, calves intended for reproduction, or calves less than 30 days old.

**Warning:** Administer the suspension subcutaneously in the ear only. Any other location is in violation of Federal Law. Do not attempt to salvage this site for animal feed or human use.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Keep out of reach of children.  
Use only as directed.



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61-50005/00/0603

Lot No.:  
Exp. Date:

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Fort Collins, CO 80524

See package insert for mixing and use directions. Store under refrigerated temperatures between 36° and 46° F (2° and 8° C).

NDC XXXXXXXXX

**Celerin™ C**  
(estradiol benzoate)

Microencapsulated Estradiol Benzoate  
Suspension Implant  
For Suckling Beef Calves

Manufactured by a non-sterilizing process  
50 - 10 mg doses to be suspended in 50 mL of diluent  
NADA 141-041, Approved by FDA

61-50110/00/0603

Lot No.:  
Exp. Date:

Manufactured for  
PR Pharmaceuticals, Inc.  
1716 Heath Parkway  
Fort Collins, CO 80524

See package insert for mixing and use directions. Store under refrigerated temperatures between 36° and 46° F (2° and 8° C).

NDC XXXXXXXXX

**STERILE DILUENT**  
For Use With  
Microencapsulated Estradiol Benzoate  
Suspension Implant

50 mL for suspension of 50 doses  
NADA 141-040, 141-041, Approved by FDA

NDC XXXXXXXXXX



1716 Heath Parkway  
Fort Collins, Colorado 80524

# Celerin C™

(estradiol benzoate)

Microencapsulated Estradiol Benzoate  
Suspension Implant

Manufactured by a non-sterilizing process



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**20 X 2.5 GRAMS**

(This case contains 20 units.  
Each unit contains 50 doses  
at 10mg EB per dose)

Store under refrigerated temperatures between 36° and 46°F (2° and 8°C).  
Avoid heat and direct sunlight.

Lot No.:  
Exp. Date:

61-50015/00/0603

NADA 141-041, Approved by FDA

# Celerin™ C

(estradiol benzoate)

Microencapsulated Estradiol Benzoate  
Suspension Implant  
Manufactured by a non-sterilizing process

For Use in Animals Only

**DESCRIPTION:** Celerin™ C contains 10mg estradiol benzoate per dose in Theraphase™ microspheres. Each dose consists of a 1mL suspension of the programmed release microspheres. The microspheres have been designed to release estradiol benzoate at a controlled rate in order to increase rate of weight gain.

This package consists of two vials, one vial containing estradiol benzoate microspheres (powder) and one vial containing diluent.

The Celerin™ C vial contains estradiol benzoate in 85:15 Poly D,L - Lactide Polymer.

The diluent vial consists of carboxymethylcellulose sodium, USP 2.5%; methylparaben, NF 0.18%; water for injection, USP qs.

Addition of the diluent to the powder results in a suspension ready for use.

**INDICATIONS:** Celerin™ C (estradiol benzoate) is indicated for increased rate of weight gain in suckling beef calves.

**Do not use in veal calves, calves intended for reproduction, or calves less than 30 days old.**

**DOSAGE AND ADMINISTRATION:** Important - Read and follow instructions as illustrated using careful aseptic technique. Never take short cuts at the expense of cleanliness.

Administer 1 dose (1mL) of the suspension subcutaneously in the ear only. A 16 to 20 gauge needle is recommended.

Agitate vial between administration of doses.

Administer the product with a suitable multi-dose syringe.

**MIXING INSTRUCTIONS:** Using normal precautions for sterility and safety, draw the entire contents of the liquid diluent into a transfer syringe. Empty contents of transfer syringe into glass vial containing the powder. Mix diluent and powder until all product is suspended. Once mixing has occurred, the suspension should be used within 72 hours. Store under refrigerated temperatures between 36° and 46°F (2° and 8° C). Avoid heat and direct sunlight. Exposure to excessive heat and direct sunlight will damage product integrity.

Do not dose the animal using the transfer syringe or needle.

61-50105/00/0303

Celerin™ and Theraphase™ are trademarks of PR Pharmaceuticals Inc.

## USE INSTRUCTIONS:

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**Restrain the Animal.**  
Accuracy of administration as well as safety to handler is best achieved by restraining animal in a squeeze chute using head restraint.

**Prepare the Administration Site.**  
Scrub the backside of the ear (administration site) using a topical germicidal solution.

**Administration Site.**  
1 dose (1mL) should be administered beneath the skin in the backside of the middle one third of the ear as illustrated in the drawing. Location for insertion of the needle is a point near the tip of the ear and a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear. Damages to large blood vessels may cause loss of the administered dose.

**Insert the Needle.**  
Firmly grasp the ear with one hand. With the other hand, insert needle point through the skin and ease forward on a lateral plane until the length of the needle is under the skin. Administer 1 dose.

**Post Administration.**  
Remove the needle and place thumb on the point of the needle insertion site. Continue to apply pressure as you slide your thumb forward from the point of insertion dispersing the fluid under the skin.



Diagram of the back of the ear. Note the blood vessels. Avoid injection into vessels. Inject in shaded area



**WARNING:** Administer the suspension subcutaneously in the ear only. Any other location is in violation of Federal Law. Do not attempt to salvage this site for animal feed or human use.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Keep out of reach of children.

**ADVERSE REACTIONS:** In clinical studies, no significant adverse reactions were observed.

**PRECAUTION:** Inadvertent intra-arterial injection of solutions intended for subcutaneous injection in the bovine ear may cause sudden death. This effect has not been studied for this product.

Store under refrigerated temperatures between 36° and 46°F (2° and 8° C). Avoid heat and direct sunlight. Exposure to excessive heat and direct sunlight will damage product integrity. Suspension should be used within 72 hours.

**HOW SUPPLIED:** Each package contains one vial of microencapsulated estradiol powder and one vial of sterile diluent for suspension. The entire package constitutes 50 X 10 mg doses of estradiol benzoate.

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