

**PLUSET- porcine follicle stimulating hormone, porcine luteinizing hormone kit  
Laboratorios Calier S.A.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**PLUSET**

**Indications:**

To induce superovulation in reproductively mature heifers or cows.

**Contraindications:**

Do not use in case of hypersensitivity to the active substance or to any of the excipients. Do not use in males and reproductively immature female cattle.

**Adverse reactions:**

Slight reduction in milk yield. Following the treatment a delayed return to heat is possible. Ovarian cysts may be formed as a result of induction of superovulation. If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

**Dosage for each species, route and method of administration:**

**Dosage for each species, route and method of administration:** Dissolve each vial of freeze-dried product with 10.5 ml of solvent. Use aseptic technique during reconstitution and when removing aliquots from the vial. Adequately clean and disinfect the vial closure prior to each entry with a sterile needle. Mix gently during reconstitution. The product is to be given by intramuscular injection only. The total recommended dose is 800 to 1000 IU in decreasing doses for 4 to 5 days. Considering the variability between animals and taking into account breed, age and reproductive status the dosing schedule should be adjusted appropriately. For heifers and beef cows a total dose of 800 IU is recommended. For dairy cows the dose could be increased to 1000 IU taking into account increasing age, parity number and dairy production.

*Recommended schedule for 800 IU in 4 days:*

Day 1*	08:00 hrs	3.0 ml i.m.	(150 UI FSH+ 150 UI LH)
	20:00 hrs	3.0 ml i.m.	(150 UI FSH+ 150 UI LH)
Day 2	08:00 hrs	2.5 ml i.m.	(125 UI FSH+ 125 UI LH)
	20:00 hrs	2.5 ml i.m.	(125 UI FSH+ 125 UI LH)
Day 3**	08:00 hrs	1.5 ml i.m.	(75 UI FSH + 75 UI LH)
	20:00 hrs	1.5 ml i.m.	(75 UI FSH + 75 UI LH)
Day 4	08:00 hrs	1.0 ml i.m.	(50 UI FSH + 50 UI LH)
	20:00 hrs	1.0 ml i.m.	(50 UI FSH + 50 UI LH)

*Recommended schedule for 1000 IU in 5 days:*

Day 1*	08:00 hrs	3.0 ml i.m.	(150 UI FSH+ 150 UI LH)
	20:00 hrs	3.0 ml i.m.	(150 UI FSH+ 150 UI LH)
Day 2	08:00 hrs	2.5 ml i.m.	(125 UI FSH+ 125 UI LH)
	20:00 hrs	2.5 ml i.m.	(125 UI FSH+ 125 UI LH)
Day 3**	08:00 hrs	2.0 ml i.m.	(100 UI FSH+ 100 UI LH)
	20:00 hrs	2.0 ml i.m.	(100 UI FSH+ 100 UI LH)
Day 4	08:00 hrs	1.5 ml i.m.	(75 UI FSH + 75 UI LH)
	20:00 hrs	1.5 ml i.m.	(75 UI FSH + 75 UI LH)
Day 5	08:00 hrs	1.0 ml i.m.	(50 UI FSH + 50 UI LH)
	20:00 hrs	1.0 ml i.m.	(50 UI FSH + 50 UI LH)

\* Corresponds to the 11<sup>th</sup> day of the oestrus cycle.

\*\* A luteolytic dose of prostaglandin F<sub>2</sub> alpha should be administered intramuscularly at 60 and/or 72 hours after the beginning of superovulation treatment.

## Withdrawal period:

Cattle: meat and offal: zero days; milk: zero hours

## Special storage precautions:

Keep out of the sight and reach of children. Store below 25°C. Reconstituted solution: store and transport refrigerated (+2°C to +8°C) and do not freeze. Keep the vial in the outer carton. Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month. Shelf-life after reconstitution according to directions: 6 days.

## Special Warnings and User Warnings:

**Special warnings:** The following recommendations for the use of this product for the induction of superovulation with adequate response should be followed:

- a. The donor animal must have had at least one normal oestrous cycle prior to the initiation of the treatment.
- b. The donor animal should not have any signs of clinical illness when treatment with this product begins. Ovarian examination should confirm the presence of a functional corpus luteum and the absence of any pathological conditions such as cystic ovarian degeneration or adhesions around the ovaries.
- c. Treatment should be initiated between day 9 and 12 of the oestrous cycle (with day 11 generally giving best results).
- d. A luteolytic dose of prostaglandin F2 alpha or analogue should be given intramuscularly at 60 and/or 72 hours after the beginning of superovulation treatment.
- e. Standing oestrus will take place 40-48 h after prostaglandin treatment and animals should be bred 12 h after the onset of standing heat and, again 12 h later with high quality semen.
- f. Following the non-surgical recovery of embryos on day 7, it is recommended to give the animals another prostaglandin treatment to assure a rapid return to heat; if not, animals should be examined 4 weeks after, to ascertain that normal ovarian activity has been restored. Breeding can take place at the first heat after superovulation, which normally is seen after 28 days.
- g. The effect of repeated treatments with this product over long periods has not been assessed for all possible schedule treatment. Therefore it is recommended not to be administered more than twice for superovulation and that at least one natural oestrus cycle be allowed to occur between the two superovulation treatments.
- h. The interval from calving to initiation of superovulation treatment should be at least 3 months.
- i. Individually variability of responses depending of age, breed, on reproductive status, could occur.

**User warnings:** Accidental self-injection of this product may cause hormonal effects in women and may harm unborn children. Care should be taken by those handling the product to avoid self-injection. In the event of accidental self-injection by women who are pregnant, or whose pregnancy status is unknown, seek medical advice immediately and show the package leaflet or label to the physician. **Use during pregnancy, lactation or lay:** Do not use during pregnancy. A slight reduction in milk yield has been observed during superovulatory heat (as in other heats) but the production in general reaches pretreatment levels within 2 weeks. **Overdose (symptoms, emergency procedures, antidotes):** It is not advisable to exceed the maximum recommended dose. High doses of FSH and LH could be associated with reduced fertilisation rate, resulting in an increase of unfertilised embryos.

## Special precautions for the disposal of unused product or waste materials, if any:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## Other information:

Carboard box with 2 glass vials of 10ml of lyophilised product and 1 glass vial of 21ml of diluent.

For animal treatment only. To be supplied only on veterinary prescription.

## Package Insert

# Pluset

## Powder and solvent for solution for injection

**Statement of the active substances and other ingredients:** White to off-white lyophilised pellet and clear and colourless solution. **One vial of lyophilised product contains:** Active substances: Follicle stimulating hormone (FSHp) 500 IU; Luteinizing hormone (LHp) 500 IU. **One vial of solvent contains:** Chlorocresol 0.021 g; Sterile, pyrogen-free, normal saline to 21 ml. **Each ml of reconstituted solution contains:** Active substance: Follicle stimulating hormone (FSHp) 50 IU; Luteinising hormone (LHp) 50 IU; Excipients: Chlorocresol 1 mg; Sterile, pyrogen-free, normal saline to 1ml.

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Ref. 300311-005

**Target species:** Cattle (reproductively mature females).

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**Date on which the package leaflet was last approved:** July 2016

**Other information:** Cardboard box with 2 glass vials of 10 ml of lyophilised product and 1 glass vial of 21 ml of diluent. For animal treatment only. To be supplied only on veterinary prescription.

IE only  
VPA 10665/001/001  
POM Prescription Only Medicine

UK only  
Vm 20634/4000  
POM-V




Marketing authorisation holder and responsible for batch release:



**LABORATORIOS CALIER, S.A.**  
C/Barcelonès, 26 (El Ramassar)  
08530 Les Franqueses del Vallès  
(Barcelona) Spain



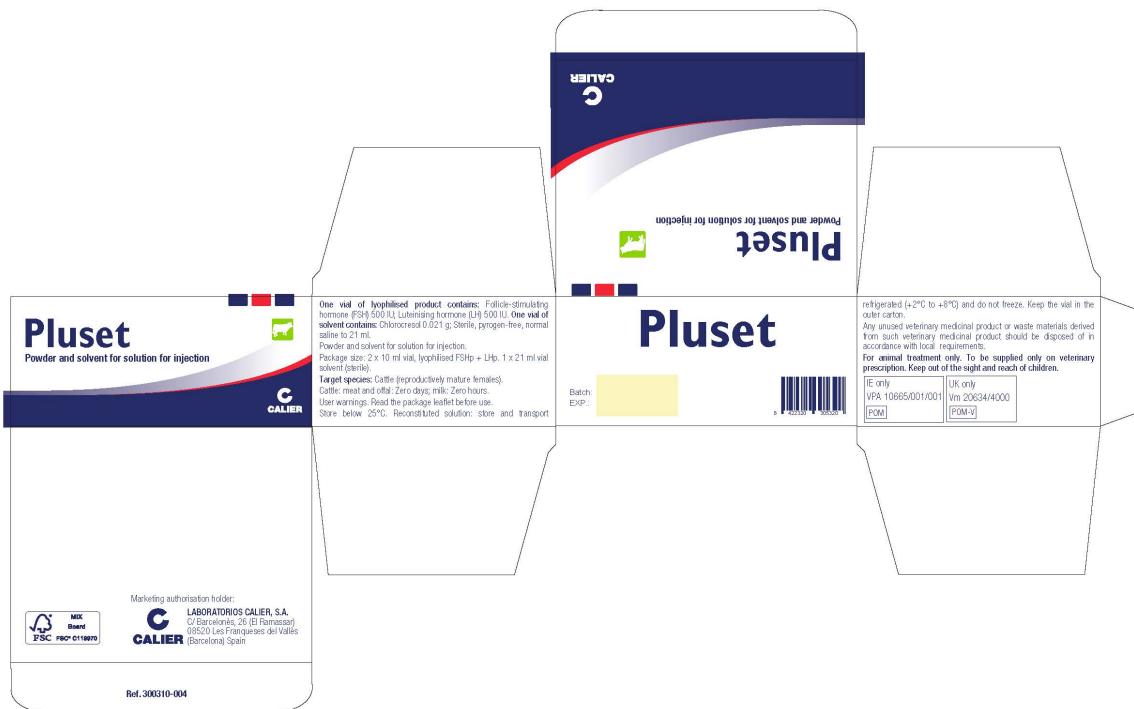
**PLUSET lyophilized powder vial label**

Batch: EXP:	<h1>Pluset</h1> 		<b>10 ml</b>	<b>Ref. 300312-007</b>
	LABORATORIOS CALIER, S.A. C/ Barcelonès, 26 (El Ramassar) 08520 Les Franqueses del Vallès (Barcelona) Spain		IE only VPA 10665/001/001 POM	UK only Vm 20634/4000 POM-V

### PLUSET Solvent vial label

Batch: EXP:	<h1>Pluset</h1> 		<b>21 ml</b>	<b>Ref. 300313-004</b>
	LABORATORIOS CALIER, S.A. C/ Barcelonès, 26 (El Ramassar) 08520 Les Franqueses del Vallès (Barcelona) Spain		IE only VPA 10665/001/001 POM	UK only Vm 20634/4000 POM-V

### PLUSET Carton Label



## PLUSET

porcine follicle stimulating hormone, porcine luteinizing hormone kit kit

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:76307-101
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76307-101-01	1 in 1 CARTON		

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	2 VIAL, MULTI-DOSE	20 mL
<b>Part 2</b>	1 VIAL, GLASS	21 mL

## Part 1 of 2

### PLUSET

follicle stimulating hormone, luteinizing hormone injection, powder, lyophilized, for solution

## Product Information

Item Code (Source)	NDC:76307-201
Route of Administration	INTRAMUSCULAR

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FOLLICLE STIMULATING HORMONE (PORCINE)</b> (UNII: 8FYM5179QJ) (FOLLICLE STIMULATING HORMONE (PORCINE) - UNII:8FYM5179QJ)	FOLLICLE STIMULATING HORMONE (PORCINE)	50 [iU] in 1 mL
<b>LUTEINIZING HORMONE</b> (UNII: 8XA4VN1LH4) (LUTEINIZING HORMONE - UNII:8XA4VN1LH4)	LUTEINIZING HORMONE	50 [iU] in 1 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76307-201-02	10 mL in 1 VIAL, MULTI-DOSE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/10/2024	

## Part 2 of 2

### PLUSET SOLVENT

physiological saline injection

## Product Information

Item Code (Source)	NDC:76307-301
Route of Administration	INTRAMUSCULAR

## Inactive Ingredients

Ingredient Name	Strength
<b>CHLOROCRESOL</b> (UNII: 36W5307109)	0.021 g in 1 mL
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>WATER</b> (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76307-301-03	21 mL in 1 VIAL, GLASS		



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/10/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/10/2024	

**Labeler** - Laboratorios Calier S.A. (460009038)

## Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Calier S.A.		460009038	analysis, manufacture, api manufacture, pack, label

Revised: 1/2024

Laboratorios Calier S.A.