PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PLUSET Powder and solvent for solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One vial of lyophilised product contains:
- Follicle-stimulating hormone (FSH) .....500 IU
- Luteinising hormone (LH) .....500 IU

One vial of solvent contains:
- Chlorocresol .....0.021 g
- Sterile, pyrogen-free, normal saline to .....21 ml

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection

4. PACKAGE SIZE

2 x 10 ml vial, lyophilised FSHp + LHp. 1 x 21 ml vial solvent (sterile)

5. TARGET SPECIES

Cattle (reproductively mature females)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle: meat and offal: Zero days
milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

User warnings
Read the package leaflet before use

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

Under veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Calier, S.A.
C/ Barcelonés, 26 (Plá del Ramassá)
Les Franqueses del Valles
Barcelona (Spain)

16. MARKETING AUTHORISATION NUMBER(S)

Vm 20634/4000

17 MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SOLVENT VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PLUSET Solvent for solution for injection.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

- Chlorocresol.....0.021 g
- Sterile, pyrogen-free, normal saline to 21 ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

21 ml

4. ROUTE(S) OF ADMINISTRATION

Only by intramuscular route

5. BATCH NUMBER

Batch:

7. EXPIRY DATE

Exp.:
Once reconstituted use by ……
Shelf life after reconstitution: 6 days

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LYOPHILISED VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PLUSET Powder for solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

- Follicle-stimulating hormone (FSH) .500 IU
- Luteinizing hormone (LH) .....500 IU

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Only by intramuscular route

5. BATCH NUMBER

Batch:

7. EXPIRY DATE

Exp.:
Once reconstituted use by ……
Shelf-life after reconstitution: 6 days

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PACKAGE LEAFLET

PLUSET
Powder and solvent for solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Laboratorios Calier, S.A.
C/ Barcelonés, 26 (Plá del Ramassá)
Les Franqueses del Valles
Barcelona (Spain)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PLUSET Powder and solvent for solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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 .....1 ml

4. INDICATIONS
To induce superovulation in reproductively mature heifers or cows.

5. 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.

6. 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.

7. TARGET SPECIES

Cattle (reproductively mature females)

8. 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 IU FSH + 150 IU LH)*
	20:00 hrs	*3.0 ml i.m.*	*(150 IU FSH + 150 IU LH)*
Day 2	*08:00 hrs*	*2.5 ml i.m.*	*(125 IU FSH + 125 IU LH)*
	20:00 hrs	*2.5 ml i.m.*	*(125 IU FSH + 125 IU LH)*
*Day 3***	*08:00 hrs*	*1.5 ml i.m.*	*(75 IU FSH + 75 IU LH)*

	20:00 hrs	*1.5 ml i.m*	*(75 IU FSH + 75 IU LH)*
Day 4	*08:00 hrs*	*1.0 ml i.m.*	*(50 IU FSH + 50 IU LH)*
	20:00 hrs	*1.0 ml i.m.*	*(50 IU FSH + 50 IU LH)*

Recommended schedule for 1000 IU in 5 days:

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

* Corresponds to the 11th day of the oestrus cycle.
** A luteolytic dose of prostaglandin F_2 alpha should be administered intramuscularly at 60 and/or 72 hours after the beginning of superovulation treatment.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Cattle: meat and offal: Zero days, milk: Zero hours

11. 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

12. 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.

13. 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

04 August 2016