

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box for lyophilisate + solvent vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PLUSET Powder and solvent for solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each vial of lyophilised contains:

Follicle-stimulating hormone (FSH)500 IU

Luteinising hormone (LH)500 IU

Each vial of solvent contains:

Chlorocresol0.021 g

Sterile, pyrogen-free, normal saline to21 ml

Once reconstituted, 1 ml of solution contains 50 IU Follicle stimulating hormone (FSHp) and 50 IU Luteinising hormone (LHp)

3. PACKAGE SIZE

2 x 10 ml vial of lyophilisate +1 x 21 ml vial of solvent.

4. TARGET SPECIES

Cattle (reproductively mature females)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:

Meat and offal: Zero days

Milk: Zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 6 days.

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use .

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Calier, S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 20634/4000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for solvent vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PLUSET Solvent for solution for injection.

2. QUANTITY PARTICULARS OF THE ACTIVE SUBSTANCES

Each vial of solvent contains:

Chlorocresol.....0.021 g
Sterile, pyrogen-free, normal saline to21 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 6 days.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of lyophilisate vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PLUSET Powder for solution for injection

2. QUANTITY PARTICULARS OF THE ACTIVE SUBSTANCES

Each vial of lyophilisate contains:

Follicle-stimulating hormone (FSH)500 IU

Luteinizing hormone (LH)500 IU

Once reconstituted, 1 ml of solution contains 50 IU Follicle stimulating hormone (FSHp) and 50 IU Luteinising hormone (LHp).

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 6 days.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

PLUSET Powder and solvent for solution for injection

2. Composition

Each vial of lyophilisate contains:

Active substances:

Follicle stimulating hormone (FSHp)500 IU

Luteinizing hormone (LHp)500 IU

Each vial of solvent contains:

Chlorocresol0.021 g

Sterile, pyrogen-free, normal saline to21 ml

Once reconstituted, 1 ml of solution contains 50 IU Follicle stimulating hormone (FSHp) and 50 IU Luteinising hormone (LHp).

Powder and solvent for solution for injection.

Powder: White to off-white lyophilised pellet

Solvent: clear and colourless solution.

3. Target species

Cattle (reproductively mature females).

4. Indications for use

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. Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

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

- The donor animal must have had at least one normal oestrous cycle prior to the initiation of the treatment.
- 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.
- Treatment should be initiated between day 9 and 12 of the oestrous cycle (with day 11 generally giving best results).
- 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.
- 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.
- 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.
- 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.
- The interval from calving to initiation of superovulation treatment should be at least 3 months.
- Individually variability of responses depending of age, breed, on reproductive status, could occur.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

Pregnancy and lactation

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.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

Major incompatibilities:

None known.

7. Adverse events

Cattle:

Undetermined frequency:	Milk yield decreased Delayed return to oestrus Ovarian cysts
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Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes 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 F₂ 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 periods

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 precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 20634/4000

Lyophilisate product:

Colourless neutral glass Eur. Ph. type I vials closed with bromobutyl and silicate stopper and FLIP-OFF seal and aluminium caps.

Solvent:

Colourless neutral glass Eur. Ph. type I vials closed with rubber peni-type stopper and FLIP-OFF seal and aluminium caps.

Package sizes:

Cardboard box with 2 vials of 10 ml of lyophilisate and 1 vial of 21 ml of diluent.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Laboratorios Calier, S.A.
C/Barcelones 26 (Pla del Ramassa)
08520 Les Franqueses del Valles
Spain

Local representatives and contact details to report suspected adverse reactions:

EGG TECHNOLOGIES INTERNATIONAL LTD
18 Springfield Park, Tisbury, Salisbury, Wiltshire SP3 6QN
Tel.: +44 (0) 1722 717478
E-mail: brian@eggtech.co.uk

17. Other information

Gavin Hall
Approved: 23 March 2026