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)

One vial of lyophilized product contains :
Active substances:
- 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

PLUSET is to be given by intramuscular injection only

5. WITHDRAWAL PERIOD(s)

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

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp.:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

9. OTHER INFORMATION

Store below 25°C.
Reconstituted solution: store and transport refrigerated (+2°C to +8°C) and do not freeze. Shelf-life after reconstitution according to directions: six days
Procured from within the EU and repackaged by the licence holder: Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

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)

One vial of lyophilized product contains :
- 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

PLUSET is to be given by intramuscular injection only

5. WITHDRAWAL PERIOD(s)

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

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp.:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

9. OTHER INFORMATION

Store below 25°C.
Reconstituted solution: store and transport refrigerated (+2°C to +8°C) and do not freeze. Shelf-life after reconstitution according to directions: six days
Procured from within the EU and repackaged by the licence holder: Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

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:

Active substances:

- 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 powder. 1 x 21 ml vial PLUSET solvent (sterile)

5. TARGET SPECIES

Bovine (reproductively mature females)

6. INDICATION(S)

To induce superovulation in reproductively mature heifers or cows.

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
Once reconstituted, use by…….

11. SPECIAL STORAGE CONDITIONS

Store below 25°C.
Reconstituted solution: store and transport refrigerated (+2°C to +8°C) and do not freeze.
Shelf-life after reconstitution according to directions: six days
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

To be supplied only on veterinary prescription

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

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Procured from within the EU and repackaged by the licence holder:
Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 43877/4007

17 MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR

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

Marketing Authorisation Holder:
Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

Manufacturer responsible for batch release:
Laboratorios Calier, S.A.
Barcelonès, 26 (Pla del Ramassà)
Les Franqueses del Vallès (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 pregnant animals

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

7. TARGET SPECIES

Bovine (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.

PLUSET 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 reach and sight 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 after the expiry date stated on the label and carton after EXP.
Shelf-life after reconstitution according to directions: six days

12. SPECIAL WARNINGS

The following recommendations for the use of PLUSET 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 PLUSET treatment.
b. The donor animal should not have any signs of clinical illness when treatment with PLUSET 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 F_2 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 PLUSET over long periods has not been assessed for all possible schedule treatment. Therefore it is recommended that PLUSET not 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.

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 pre-treatment levels within 2 weeks.

Overdose (symptoms, emergency procedures, antidotes), if necessary
It is not advisable to exceed the maximum recommended dose. High doses of FSH and LH could be associated with reduced fertilization rate, resulting in an increase of unfertilized embryos.

For Animal Treatment Only

User Warnings
Care should be taken when handling the product to avoid self-injection. Accidental self-injection may cause biological effects in women and to the unborn child. In the event of accidental self-injection in women who are pregnant, or whose pregnancy status is unknown, seek medical advice.

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

2016

15. OTHER INFORMATION

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

POM-V

Vm 43877/4007

Approved: 28 June 2016