PLUSET- porcine follicle stimulating hormone, porcine luteinizing hormone
Minitube of America, Inc.

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.

PLUSET Swine pituitary gonadotrophins

DESCRIPTION

PLUSET is a mixture of swine pituitary gonadotrophins used for the induction of multiple ovulations (superovulation). The use of standardized concentrations for both gonadotrophins guarantees a consistent quality of the product and eliminates possible variability in effectiveness from one lot to another. In the absence of an International Standard for the porcine gonadotrophin, dosing is carried out using the International Standard for human urine FSH and LH.

PROPERTIES AND ACTION

Ovarian stimulation with exogenous Follicle-Stimulating Hormone (FSH) allows a greater number of *ova* to be produced than normally produced in a single reproductive cycle.

The pituitary hormone extract contains variable levels of Follicle-Stimulating Hormone (FSH) and Luteinizing Hormone (LH).

Clearly in order to obtain proper and effective superovulation which provides satisfactory results involving a high number of living embryos, it is necessary to carry out a treatment that guarantees the activation and progress of multiple follicle maturation in the most "physiological" and repeatable way possible.

Thus, given that it influences the activity of FSH, it is important to have a defined level of LH present.

PLUSET is manufactured in a method chosen to ensure that the defined level of LH content is consistently mantained.

Kinetic studies of FSH and LH in the bloodstream of bovine has shown a half-life of 150 minutes for FSH and a half-life of 40 minutes for LH.

ANIMAL SPECIES AND INDICATIONS

To induce superovulation in reproductively mature heifers or cows.

CONTRA-INDICATIONS

Do not use in pregnant animals.

WARNINGS

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.

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.

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.

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.

DOSAGE AND ADMINISTRATION ROUTE

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 following treatment schedule is recommended for the induction of superovulation in the cow:

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. It is therefore recommended to seek veterinary advice on appropriate dosing patterns. 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.*

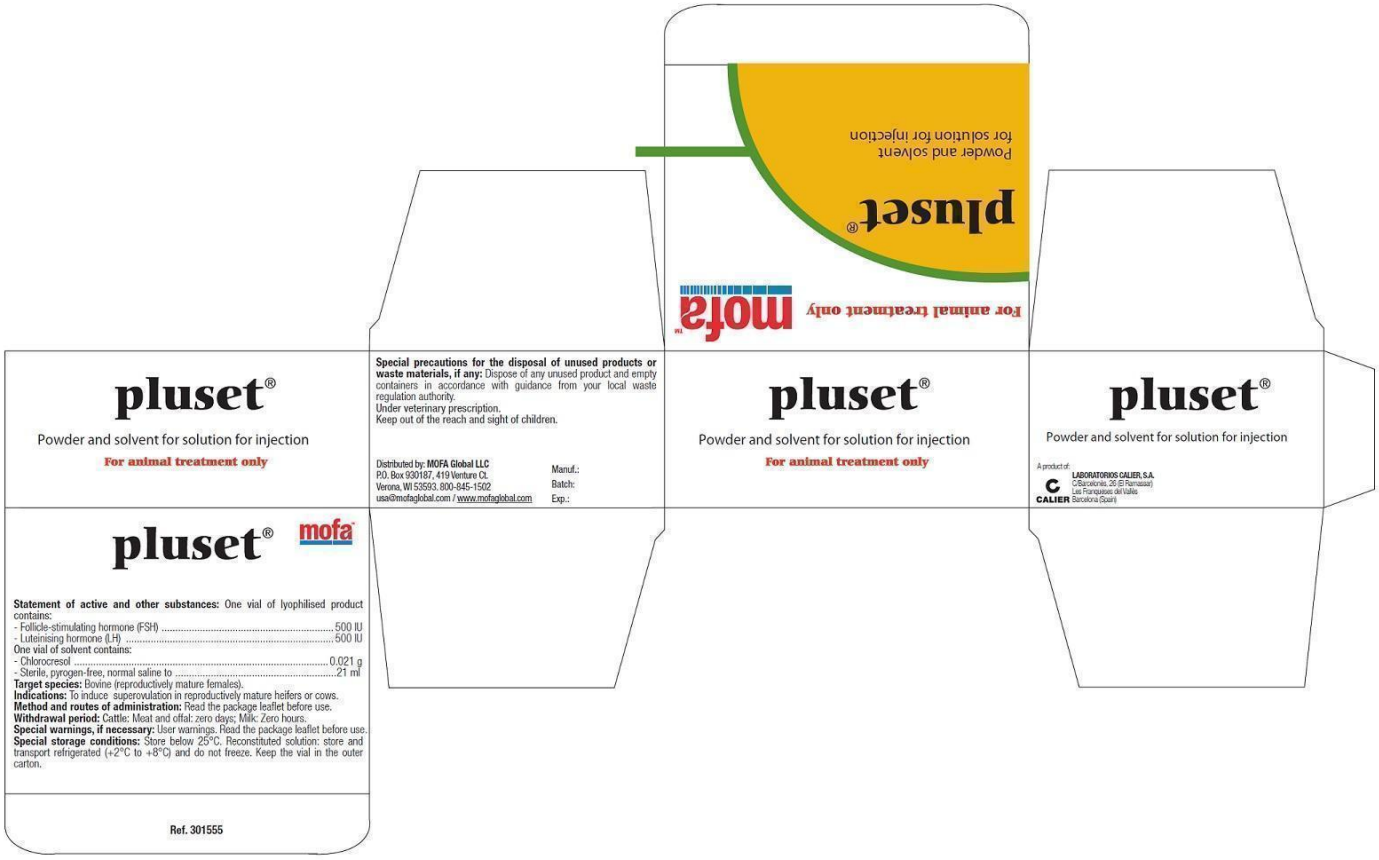
STORAGE

Keep out of the reach and sight of children. Store below 25ºC. Reconstituted solution: store and transport refrigerated (+2ºC to +8ºC) 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.

CONTENTS

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

Pluset box



PLUSET

porcine follicle stimulating hormone, porcine luteinizing hormone kit

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:54129-178

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54129-178-09	1 in 1 CARTON		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	2 VIAL, MULTI-DOSE	20 mL
Part 2	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:54129-180
Route of Administration	INTRAMUSCULAR

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Follitropin (UNII: 076WHW89TW) (Follitropin - UNII:076WHW89TW)	Follitropin	50 [iU] in 1 mL
Lutropin alfa (UNII: 3JGY52XJNA) (Lutropin alfa - UNII:3JGY52XJNA)	Lutropin alfa	50 [iU] in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		2 in 1 CARTON		
1	NDC:54129-180-07	10 mL in 1 VIAL, MULTI-DOSE; Number of Units = 2		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/01/2005	

Part 2 of 2

PLUSET DILUENT

physiological saline injection

Product Information	
Item Code (Source)	NDC:54129-301
Route of Administration	INTRAMUSCULAR

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium Chloride (UNII: 451W47IQ8X)	
Water (UNII: 059QF0KO0R)	
CHLOROCRESOL (UNII: 36W53O7109)	1 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54129-301-34	21 mL in 1 VIAL, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/01/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/01/2005	

Labeler - Minitube of America, Inc. (555636117)

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
KERN PHARMA S.L.		467325122	manufacture

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