

**PLUSET FLEX H- 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.*

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**PLUSET FLEX H Swine pituitary gonadotrophins**

**DESCRIPTION**

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

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**

For the induction of superovulation in bovine females.

**CONTRA-INDICATIONS**

There are no ascertained contra-indications.

**WARNINGS**

Do not slaughter animals for human consumption for 10 days following the last injection. Broken or cracked vials should be handled with gloves.

**KEEP OUT OF THE REACH OF CHILDREN**

**DOSAGE AND ADMINISTRATION ROUTE**

The injection of PLUSET FLEX H must be intra-muscular (i.m.). Subcutaneous administration results in

an irregular absorption and must be avoided.

Reconstitute each vial of PLUSET FLEX H with 10 ml of the PLUSET diluent provided. Reconstitution and subsequent withdrawal of product should be performed using strict aseptic technique.

Dispense the diluent into the lyophilizate bottle to completely resuspend the contents. Label the diluent bottle appropriately and mix thoroughly before use.

**Regimen 1: Mature cow**

<b>Day</b>	<b>AM</b>	<b>PM</b>
1	4 ml	4 ml
2	3 ml	3 ml
3	2 ml	1.5 ml
4	1.5 ml	1 ml

**Regimen 2: Heifers**

<b>Day</b>	<b>AM</b>	<b>PM</b>
1	3 ml	3 ml
2	2 ml	2 ml
3	1.5 ml	1.5 ml
4	1 ml	1 ml

**STORAGE**

The lyophilised product is stable for 24 months stored at temperature below 25 °C. Once the preparation is prepared, the activity of the FSH and LH remain unchanged for at least six days, on condition that the preparation is stored at a temperature between 2 - 8 °C and the normal precautions for maintaining sterility are followed.

**CONTENTS**

Each box contains 2 vials with 525 IU FSH/175 IU LH per vial. Includes 1 x 20 ml diluent (sterile) vial.

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For veterinary use only

FSHp-LHp

**pluset<sup>®</sup> FLEX H**

minitube



**pluset<sup>®</sup> FLEX H**  
 FSHp-LHp

For veterinary use only

**pluset<sup>®</sup> FLEX H**  
 FSHp-LHp

For veterinary use only

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**pluset<sup>®</sup> FLEX H**  
 FSHp-LHp

**Swine pituitary gonadotrophins**

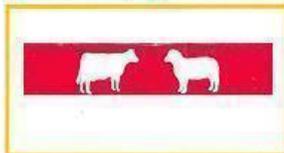
**Indications:**  
 For the induction of superovulation in bovines

**Animal species:**  
 Bovines and breeding animals in general.

**Contra-indications:**  
 None reported.

**Contents:**  
 525 IU of FSH & 175 IU of LH in one vial, 2 vials per box (includes 20ml Diluent)

**Recommended reconstitution and usage:**  
 Refer to the package insert for recommended method of reconstitution and usage.



Distributed by



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**DISPOSAL:**  
 Unused product must be disposed of in such a manner as to prevent accidental contact or spillage.

**STORAGE:**  
 Store below 25 °C.

**WARNINGS:**  
 Do not slaughter animals for human consumption for 10 days following the last injection. Broken or cracked vials should be handled with gloves.

KEEP OUT OF THE REACH OF CHILDREN

Ref.:300733

**PLUSET FLEX H**

porcine follicle stimulating hormone, porcine luteinizing hormone kit

**Product Information**

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:54129-307
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54129-307-33	1 in 1 CARTON		

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 VIAL, GLASS	20 mL
Part 2	1 VIAL, GLASS	20 mL

## Part 1 of 2

### PLUSET FLEX H

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

## Product Information

Item Code (Source)	NDC:54129-308
Route of Administration	INTRAMUSCULAR

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Follitropin</b> (UNII: 076 WHW89TW) (Follitropin - UNII:076 WHW89TW)	Follitropin	52.5 [iU] in 1 mL
<b>Lutropin alfa</b> (UNII: 3JGY52XJNA) (Lutropin alfa - UNII:3JGY52XJNA)	Lutropin alfa	17.5 [iU] in 1 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54129-308-31	10 mL in 1 VIAL, GLASS		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/01/2010	

## Part 2 of 2

### PLUSET DILUENT

physiological saline injection

**Product Information**

<b>Item Code (Source)</b>	NDC:54129-200
<b>Route of Administration</b>	INTRAMUSCULAR

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>Sodium Chloride</b> (UNII: 451W47IQ8X)	
<b>Water</b> (UNII: 059QF0K00R)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:54129-200-34	20 mL in 1 VIAL, GLASS		

**Marketing Information**

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

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other		09/01/2010	

**Labeler** - Minitube of America, Inc. (555636117)**Establishment**

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

**Establishment**

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

Revised: 5/2013

Minitube of America, Inc.