CLIENT INFORMATION SHEET

PLUSET (follicle stimulating hormone/luteinizing hormone) is not an FDA-approved product but is authorized for marketing in in a number of countries worldwide. PLUSET is being temporarily imported to the U.S. to address a shortage of Folltropin (porcine pituitary-derived follicle stimulating hormone for injection) for use in inducing superovulation in reproductively mature heifers or cows.

Although the indications of Pluset and Folltropin are similar, the composition and concentration of active ingredients are different, and so are the doses and dosage regimens of the two products. **Some important considerations when using PLUSET are described below; however, please read the entire PLUSET label and package insert prior to use.**

To be supplied only on veterinary prescription.

PLUSET Powder and diluent for injection

PLUSET 500 IU/500 IU powder and diluent for solution for injection for cattle. Follicle stimulating hormone (FSH), luteinizing hormone (LH) presented as a white to off-white lyophilized pellet and clear and colorless solution.

One vial of lyophilized product contains:
Active substances:
- Follicle stimulating hormone (FSH) ..... 500 IU
- Luteinizing hormone (LH) ..... 500 IU

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

Each ml of reconstituted solution contains:
Active substance:
Follicle stimulating hormone (FSH) ..... 50 IU
Luteinizing hormone (LH) ..... 50 IU
Excipients:
Chlorocresol ..... 1 mg
Sterile, pyrogen-free, normal saline to ..... 1 ml

POTENTIAL ADVERSE DRUG EVENTS

- Slight reduction in milk yield
- Following treatment, a delayed return to heat is possible.
- Ovarian cysts may be formed as a result of the induction of superovulation.

If you notice any adverse effects or other effects not mentioned in this Client Information Sheet or the package insert, please inform your veterinarian. To report a suspected adverse drug event (side effect) or a product quality problem, contact Solvet by calling 1-403-271-2920. Adverse drug events and product quality problems may also be reported directly to FDA by completing the online form available at http://www.fda.gov/reportanimalae or by requesting a copy of the form at 1-888-FDA-VETS.

ROUTE AND METHOD OF ADMINISTRATION

- Dissolve each vial of freeze-dried product with 10.5 ml of solvent.
- Mix gently during reconstitution.
- Administer by intramuscular injection only.

The dose administered should be as stated in the PLUSET package insert.

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.

The following table indicates the labeled dosages for PLUSET.

	(Schedule for 800 IU in 4 days)		(Schedule for 1000 IU in 5 days)	
	mL	IU FSH/LH	mL	IU FSH/LH
Time of Day	**AM / PM**	**AM / PM**	**AM / PM**	**AM / PM**
Day 1	3.0/3.0	150/150	3.0/3.0	150/150
Day 2	2.5/2.5	125/125	2.5/2.5	125/125
Day 3*	1.5/1.5	75/75	2.0/2.0	100/100
Day 4	1.0/1.0	50/50	1.5/1.5	75/75
Day 5			1.0/1.0	50/50
Total	**16.0**	**800**	**20**	**1000**

* A luteolytic dose of prostaglandin F2 alpha should be administered intramuscularly at 60 and/or 72 hours after the beginning of superovulation treatment.

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

USER SAFETY WARNINGS:

Keep out of sight and reach of children.

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 Client Information Sheet and package insert to the physician.

SPECIAL STORAGE PRECAUTIONS

- Store unreconstituted product below 77° F
- Store and transport reconstituted solution refrigerated (35.6° to 46.4° F) and do not freeze.
- Keep the vials in the outer carton.
- Shelf-life after reconstitution according to directions: 6 days