Perform FTAI 0 to 24 hours after the second dose of FACTREL.

Administer LUTALYSE (25 mg dinoprost, as dinoprost tromethamine injection) to cows on detected estrus using standard herd practices.

For use with LUTAL YSE® (dinoprost tromethamine injection) Injection to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI).

**INDICATIONS FOR USE**

For the treatment of ovarian follicular cysts in lactating dairy cows, beef cows, and replacement dairy and beef heifers. The treatment effect of FACTREL Injection has the identical amino acid sequence as endogenous gonadorelin, which is produced by the hypothalamus and causes the release of the gonadotropins luteinizing hormone (LH) and follicle-stimulating hormone (FSH) from the anterior pituitary.

FACTREL Injection has the identical amino acid sequence as endogenous gonadorelin, 5-omega-Pro-His-Pro-Pro-Arg-Leu-Arg-Pro-Gly-NH2, with identical physiological activities. The molecular weight of gonadorelin is 1219 (1 HCI) expressed as hydrochloride) per mL in aqueous formulation.

FACTREL Injection is a sterile solution containing 50 mcg/mL of gonadorelin, 0.6% sodium chloride and 2% benzyl alcohol (as a preservative). FACTREL Injection was used alone for treatment of cystic ovaries.

**MECHANISM OF ACTION**

Follicular cysts are enlarged non-ovulatory follicles resulting from a malfunction of the neuroendocrine mechanism controlling follicular maturation and ovulation. Effective administration of gonadorelin (FACTREL) reduces the number of days from treatment to ovulation. FACTREL Injection induces release of endogenous luteinizing hormone (LH) to produce this effect.

Gonadorelin, through release of LH has been demonstrated to induce ovulation of dominant ovarian follicles present on the bovine ovary during the estrous cycle. Administration of FACTREL injection has the same effect.

**WARNINGS AND PRECAUTIONS**

For use in animals only. Not for human use. Keep out of reach of children.

**RESIDUE WARNINGS**

No withdrawal periods or residue considerations is required when used according to labeling.

**EFFECTIVENESS**

For the treatment of ovarian follicular cysts in lactating dairy cows, beef cows, and replacement dairy and beef heifers is a reduction in the number of days to first estrus.

There were no significant differences in days from treatment to conception, frequency of cows conceiving at first or subsequent heats, or conception rates among treated or non-treated control animals, when FACTREL was administered intramuscularly as a single injection.

**SAFETY AND TOLERABILITY**

FACTREL Injection has been labeled for use in cattle only. For use in animals only. Not for human use. Keep out of reach of children.

**HOW SUPPLIED**

FACTREL Injection (gonadorelin injection), 50 mcg/mL is available in 20 mL and 50 mL multi-dose vials (box of one).

**STORAGE CONDITIONS**

Store at refrigerator temperatures 2° to 8°C (36° to 46°F) with vacuums permitted to 25°C (77°F). See contents after 1 month of first sale purchase.

**APPROVED BY FDA UNDER NADA # 139-237**

**CONTACT INFORMATION**

For a copy of the Safety Data Sheet or to report adverse reactions, call Zoetis Inc. at 1-888-963-8471. For additional information about adverse drug experience reporting for veterinary medicine, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimal.