Clinical, a slight transitory increase in heart rate was detected. There was no unequivocal effect of dinoprost on the organ weights, and gross plus microscopic measurements following treatment with single doses of 16, 30, 130, and 1,000 mg/kg. Subcutaneous administration to adult mares (weighing 320 to 485 kg; 2 to 20 years of age) for 6, 7 and 8 or 10 and 11 or 13, 14 and 16, and 17 or 19 or 21 or 25 and 30 days did not result in detectable lesions. There was no evidence of toxicological effects following injection (25 mg luteolytic dose vs. 250 mg dinoprost tromethamine, respectively). Sweating was temporary after injection. Neither heart rate nor respiration rates were altered significantly by dinoprost. There was no evidence of behavioral changes. The excessive bleeding of the skin from the entire body and the appearance of a white tinge following injection for the 10 to 15 mg dosage were immediate but ceased within 24 hours after injection and were attributed to the abnormal teratogenic properties of the drug.

Mares: Dinoprost tromethamine was administered to adult mares (weighing 320 to 425 kg; 2 to 20 years) at the rates of 500, 1,000, 2,000, 4,000, and 8,000 mg/day for 1 or 2 days. Route of administration for each dose group was both intramuscularly (2 mares) and subcutaneously (2 mares). Changes were detected in all treated groups (for clinical reduced sensitivity to labor, locomotor excitement, diarrhea, sweating, hyperthermia, labored inspiration), blood chemistry (reduced cholesterol, total bilirubin, LDH, and glucose), and histopathology (enlarged eosophagus, increased hemorrhage, hemorrhage, and neutrophilic exudate). Changes in the 10 mg dose, and to a lesser extent, the 200 mg dose groups were transient in nature. None of the changes observed by dinoprost tromethamine were able to persist abnormal teratogenic effects following termination of the side effects. There was no evidence of adverse effects in pregnant mares following treatment with a dose of 400 mg or 800 mg exhibited more profound symptoms. The excessive swelling of the skin from the entire body and the appearance of a white tinge following injection for the 10 mg dosage group were detected. The slight diarrhea, slight electrolyte imbalance (decreased sodium and potassium), dehydration, and minor bleeding was observed in the ovary and uterine horns containing fluid but not observed in any other organs. There was no evidence of toxicological effects following injection. The excessive bleeding of the skin from the entire body and the appearance of a white tinge following injection and were attributed to the abnormal teratogenic properties of the drug.

Mares: Dinoprost tromethamine was administered to adult mares (weighing 320 to 425 kg; 2 to 20 years) at the rates of 500, 1,000, 2,000, 4,000, and 8,000 mg/day for 1 or 2 days. Route of administration for each dose group was both intramuscularly (2 mares) and subcutaneously (2 mares). Changes were detected in all treated groups (for clinical reduced sensitivity to labor, locomotor excitement, diarrhea, sweating, hyperthermia, labored inspiration), blood chemistry (reduced cholesterol, total bilirubin, LDH, and glucose), and histopathology (enlarged eosophagus, increased hemorrhage, hemorrhage, and neutrophilic exudate). Changes in the 10 mg dose, and to a lesser extent, the 200 mg dose groups were transient in nature. None of the changes observed by dinoprost tromethamine were able to persist abnormal teratogenic effects following termination of the side effects. There was no evidence of adverse effects in pregnant mares following treatment with a dose of 400 mg or 800 mg exhibited more profound symptoms. The excessive swelling of the skin from the entire body and the appearance of a white tinge following injection for the 10 mg dosage group were detected. The slight diarrhea, slight electrolyte imbalance (decreased sodium and potassium), dehydration, and minor bleeding was observed in the ovary and uterine horns containing fluid but not observed in any other organs. There was no evidence of toxicological effects following injection. The excessive bleeding of the skin from the entire body and the appearance of a white tinge following injection and were attributed to the abnormal teratogenic properties of the drug.
and discontinue the vial stopper prior to entry with a sterile needle and syringe. Use only sterile needles, and use each needle only once.

To vail stoppers should be entered more than 20 times. For this reason, the 100 mL bottle should only be used with the 30 mL bottle. The 30 mL bottle may be used for cattle, swine, or mares.

**Cattle:**

1. Estrus Synchronization in Beef Cows, Beef Heifers, and Replacement Heifers

**LUTALYSE** Injection is used to control the timing of estrus and ovulation in estrous cycling cattle that are not a corpus luteum at estrus. Use with EAZI-BREED™ CIDR® (progesterone intravaginal insert) Cattle Insert for estrus synchronization of first postpartum estrus in such cattle. 

- Administer one dose of FACTREL Injection (2-4 mL) on Day 0.
- Administer one dose of FACTREL Injection (25 mg dinoprost) intramuscularly either once or twice at 12 to 14 day interval. With the single injection, cattle should be bred at the usual time relative to estrus. In instances where a second injection can be bred after the second injection either at the usual time relative to detected estrus or at about 6 months after the second injection of **LUTALYSE** Injection. Estrus is expected to occur 1 to 2 days after injection of a corpus luteum was present. Cattle that do not become pregnant to breeding at estrus on days 1 to 2 after injection will be expected to return to estrus in about 18 to 21 days.

2. For Unobserved ( Silent) Estrus in Lactating Dairy Cows with a Corpus Luteum, inject a dose of 5 mL **LUTALYSE** Injection (25 mg dinoprost) intramuscularly 12 to 14 days after the last milk was expressed. If estrus has not been observed by 80 hours use with EAZI-BREED™ CIDR® (progesterone intravaginal insert) Cattle Insert for estrus synchronization of first postpartum estrus in such cattle.

**LUTALYSE** Injection is used for its abortifacient effect in beef cows, for its abortifacient effect in mares, and for Treatment of Pyometra (chronic infections associated with injection of **LUTALYSE** Injection was reported but was not anaphylactic reaction of several hundred mares treated with **LUTALYSE** Injection. An interesting observation in the above study was that the radioactive dose of 3H PGF 2 alpha was rapidly metabolized in the bovine vascular system, gastrointestinal tract, respiratory and smooth muscle stimulation in certain species.

**Adverse Reactions:**

Cattle: Limitation in reported has been reported in some instances.

Swine: The most frequently observed side effects were syncope and pruritus, slight incoordination, nesting behavior, irriating, urination, defecation, abdominal noises, restlessness, salivation, and anaphylaxis. Complications have been transient in all cases observed and have been supportive care. Many mares do not exhibit regular estrous cycles and may give a positive response to treatment due to early fetal death and resorption, or as a result of “pregnancy stress”, there may be serum progesterone levels consistent with a functional corpus luteum. Treatment of such mares with **LUTALYSE** Injection usually results in regression of the corpus luteum followed by estrus and/or treatment. “Anestrous” mares which abort after treatment with **LUTALYSE** Injection do not result in estrus due to presence of functional endometrial cups.

**Warnings and Precautions:**

User Safety: Not for human use. Keep out of the reach of children. Women levels consistent with a functional corpus luteum. Treatment of such mares with **LUTALYSE** Injection usually results in regression of the corpus luteum followed by estrus and/or treatment. “Anestrous” mares which abort after treatment with **LUTALYSE** Injection do not result in estrus due to presence of functional endometrial cups.

- **ADVERSE REACTIONS**

Cattle: Limited in reported has been reported in some instances.

Swine: The most frequently observed side effects were syncope and pruritus, slight incoordination, nesting behavior, irriating, urination, defecation, abdominal noises, restlessness, salivation, and anaphylaxis. Complications have been transient in all cases observed and have been supportive care. Many mares do not exhibit regular estrous cycles and may give a positive response to treatment due to early fetal death and resorption, or as a result of “pregnancy stress”, there may be serum progesterone levels consistent with a functional corpus luteum. Treatment of such mares with **LUTALYSE** Injection usually results in regression of the corpus luteum followed by estrus and/or treatment. “Anestrous” mares which abort after treatment with **LUTALYSE** Injection do not result in estrus due to presence of functional endometrial cups.

**Animal Safety Warnings:**

- **WARNINGS AND PRECAUTIONS**

User Safety: Not for human use. Keep out of the reach of children. Women levels consistent with a functional corpus luteum. Treatment of such mares with **LUTALYSE** Injection usually results in regression of the corpus luteum followed by estrus and/or treatment. “Anestrous” mares which abort after treatment with **LUTALYSE** Injection do not result in estrus due to presence of functional endometrial cups.

**ADVERSE REACTIONS**

Cattle: Limited in reported has been reported in some instances.

Swine: The most frequently observed side effects were syncope and pruritus, slight incoordination, nesting behavior, irriating, urination, defecation, abdominal noises, restlessness, salivation, and anaphylaxis. Complications have been transient in all cases observed and have been supportive care. Many mares do not exhibit regular estrous cycles and may give a positive response to treatment due to early fetal death and resorption, or as a result of “pregnancy stress”, there may be serum progesterone levels consistent with a functional corpus luteum. Treatment of such mares with **LUTALYSE** Injection usually results in regression of the corpus luteum followed by estrus and/or treatment. “Anestrous” mares which abort after treatment with **LUTALYSE** Injection do not result in estrus due to presence of functional endometrial cups.

**Animal Safety Warnings:**

- **WARNINGS AND PRECAUTIONS**

User Safety: Not for human use. Keep out of the reach of children. Women levels consistent with a functional corpus luteum. Treatment of such mares with **LUTALYSE** Injection usually results in regression of the corpus luteum followed by estrus and/or treatment. “Anestrous” mares which abort after treatment with **LUTALYSE** Injection do not result in estrus due to presence of functional endometrial cups.

**ADVERSE REACTIONS**

Cattle: Limited in reported has been reported in some instances.

Swine: The most frequently observed side effects were syncope and pruritus, slight incoordination, nesting behavior, irriating, urination, defecation, abdominal noises, restlessness, salivation, and anaphylaxis. Complications have been transient in all cases observed and have been supportive care. Many mares do not exhibit regular estrous cycles and may give a positive response to treatment due to early fetal death and resorption, or as a result of “pregnancy stress”, there may be serum progesterone levels consistent with a functional corpus luteum. Treatment of such mares with **LUTALYSE** Injection usually results in regression of the corpus luteum followed by estrus and/or treatment. “Anestrous” mares which abort after treatment with **LUTALYSE** Injection do not result in estrus due to presence of functional endometrial cups.

**Animal Safety Warnings:**

- **WARNINGS AND PRECAUTIONS**

User Safety: Not for human use. Keep out of the reach of children. Women levels consistent with a functional corpus luteum. Treatment of such mares with **LUTALYSE** Injection usually results in regression of the corpus luteum followed by estrus and/or treatment. “Anestrous” mares which abort after treatment with **LUTALYSE** Injection do not result in estrus due to presence of functional endometrial cups.

**ADVERSE REACTIONS**

Cattle: Limited in reported has been reported in some instances.

Swine: The most frequently observed side effects were syncope and pruritus, slight incoordination, nesting behavior, irriating, urination, defecation, abdominal noises, restlessness, salivation, and anaphylaxis. Complications have been transient in all cases observed and have been supportive care. Many mares do not exhibit regular estrous cycles and may give a positive response to treatment due to early fetal death and resorption, or as a result of “pregnancy stress”, there may be serum progesterone levels consistent with a functional corpus luteum. Treatment of such mares with **LUTALYSE** Injection usually results in regression of the corpus luteum followed by estrus and/or treatment. “Anestrous” mares which abort after treatment with **LUTALYSE** Injection do not result in estrus due to presence of functional endometrial cups.

**Animal Safety Warnings:**

- **WARNINGS AND PRECAUTIONS**

User Safety: Not for human use. Keep out of the reach of children. Women levels consistent with a functional corpus luteum. Treatment of such mares with **LUTALYSE** Injection usually results in regression of the corpus luteum followed by estrus and/or treatment. “Anestrous” mares which abort after treatment with **LUTALYSE** Injection do not result in estrus due to presence of functional endometrial cups.