GLEPTOFORTE- gleptoferron injection
Ceva Sante Animale

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ANADA 200-587, Approved by FDA
GleptoForte™
(gleptoferron)
200 mg/mL of iron
Solution for intramuscular injection
NOT FOR USE IN HUMANS
KEEP OUT OF REACH OF CHILDREN

DESCRIPTION: GleptoForte™ is a sterile aqueous colloidal solution of gleptoferron, a macromolecular complex of ferric hydroxide and dextran glucoheptonic acid. Each milliliter contains 200 mg of elemental iron. The solution contains 0.5% phenol as preservative.

ACTIONS: GleptoForte™ contains gleptoferron which provides a rapidly absorbed and readily utilizable form of iron for the prevention and treatment of baby pig anemia.

INDICATIONS: GleptoForte™ is recommended for both the routine prevention and treatment of baby pig anemia due to iron deficiency.

NOTICE: Organic iron preparations injected intramuscularly into pigs beyond 4 weeks of age may cause staining of the muscle tissue.

DOSAGE AND ADMINISTRATION: GleptoForte™ is for intramuscular use only. Prevention: 1 mL (200 mg iron) per pig on or before 3 days of age. Treatment: 1 mL (200 mg iron) per pig as soon as signs of deficiency appear.

WITHDRAWAL PERIODS: No withdrawal period is required when used according to labeling.

ANIMAL SAFETY WARNINGS AND PRECAUTIONS: Occasionally pigs may show a reaction to injectable iron, clinically characterized by prostration with muscular weakness. In extreme cases, death may occur.

For a copy of the Safety Data Sheet (SDS) or to report suspected adverse drug events, contact CEVA at 1-800-999-0297.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/AnimalVeterinary/SafetyHealth.

HOW TO INJECT:

What to use
1. GleptoForte™ (gleptoferron) injection
2. Ordinary 10 mL syringe or multi dose injection syringe
3. ½ inch-20 gauge needle
4. Disinfectant (rubbing alcohol or tincture of iodine)

Where to use:
GleptoForte™ is for intramuscular use. The preferred site of injection is the ham muscle. Push the needle directly into the ham to approximately a one-half (1/2) inch depth. Avoid injection into a blood vessel. This is best avoided by pulling back slightly on the plunger after the needle is seated in the ham. If properly located, resistance will be offered to this effort. If the plunger is pulled back easily, remove
Step 1 The pig is held under-arm, between knees, or by an assistant. Disinfect the injection site. Pull down skin and fat with thumb as shown. Approximately halfway along a line between the anus and the thumb is the best injection site.

Step 2 Before injecting GleptoForte™, point the needle upward and gently press the plunger to expel all air from syringe. The needle is inserted at right-angle to the skin into the ham approximately a one-half (1/2) inch depth and the injection made.
Step 3 Use a new needle between each stopper puncture. Protect the needle from contamination and disinfect between animal injections.

HOW SUPPLIED:
GleptoForte™ (gleptoferron) injection is available in 100 mL multi-dose vials.

STORAGE: Store at 20°C - 25°C (68°F - 77°F). Do not freeze. Use within 28 days of first puncture and puncture a maximum of ninety-five (95) times.

Principal Display Panel - 100 mL Bottle Label
GleptoForte™
(gleptoferron) 200 mg/mL of iron
Solution for intramuscular injection
For the prevention and treatment of Baby Pig Anemia due to iron deficiency

NOT FOR USE IN HUMANS
KEEP OUT OF REACH OF CHILDREN
ANADA 200-587, Approved by FDA.
Net Contents: 100mL
## GLEPTOFORTE

gleptoferron injection

### Product Information

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<th>Product Type</th>
<th>OTC ANIMAL DRUG</th>
<th>Item Code (Source)</th>
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<td>Route of Administration</td>
<td>INTRAMUSCULAR</td>
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### Active Ingredient/Active Moiety

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<td>GLEPTOFERRON (UNII: 898723IQHQ) (GLEPTOFERRON - UNII:898723IQHQ)</td>
<td>GLEPTOFERRON</td>
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### Packaging

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### Marketing Information

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**Labeler** - Ceva Sante Animale (261126049)

**Registrant** - Ceva Sante Animale (261126049)

**Establishment**

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Revised: 9/2018

Ceva Sante Animale