

**GLEPTOFORTE- gleptoferron injection**  
**Ceva Sante Animale**

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**GleptoForte®**

**(gleptoferron)**

**200 mg/mL of iron**

**Solution for intramuscular injection**

**NOT FOR USE IN HUMANS**

**KEEP OUT OF REACH OF CHILDREN**

**Approved by FDA under ANADA # 200-587**

**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>.

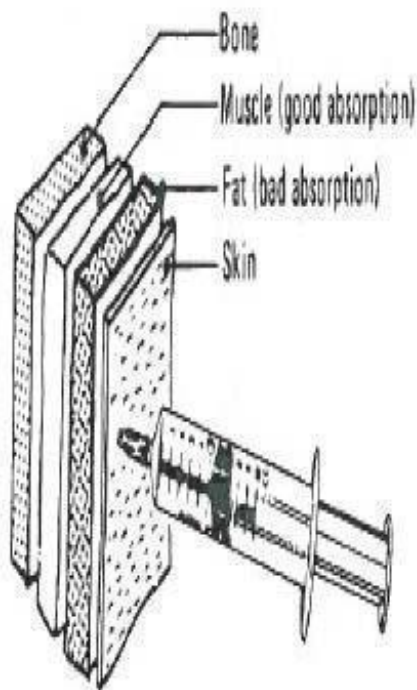
**HOW TO INJECT:**

What to use

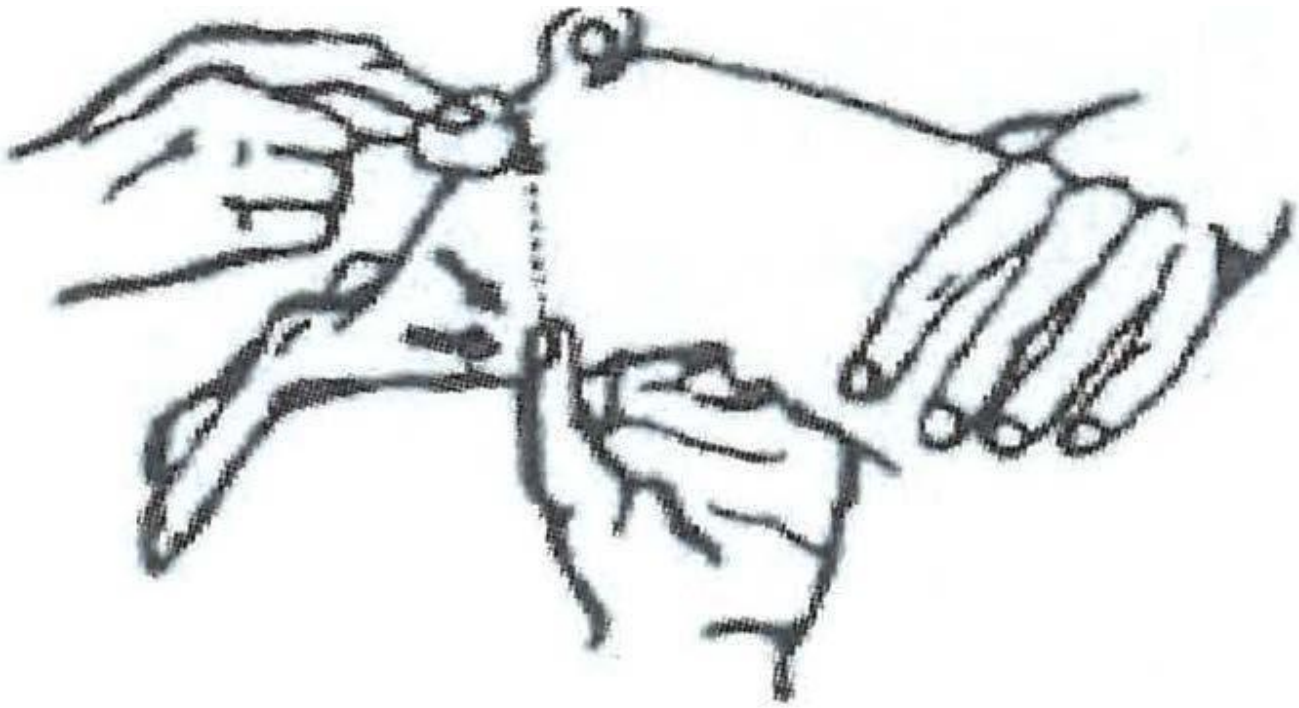
1. GleptoForte® (gleptoferron) injection
2. Ordinary 10 mL syringe with 18-gauge needle or smaller, or dosage delivery device with 4-gauge draw off spike or smaller
3. Disinfectant (rubbing alcohol or tincture of iodine)

### **Where to use:**

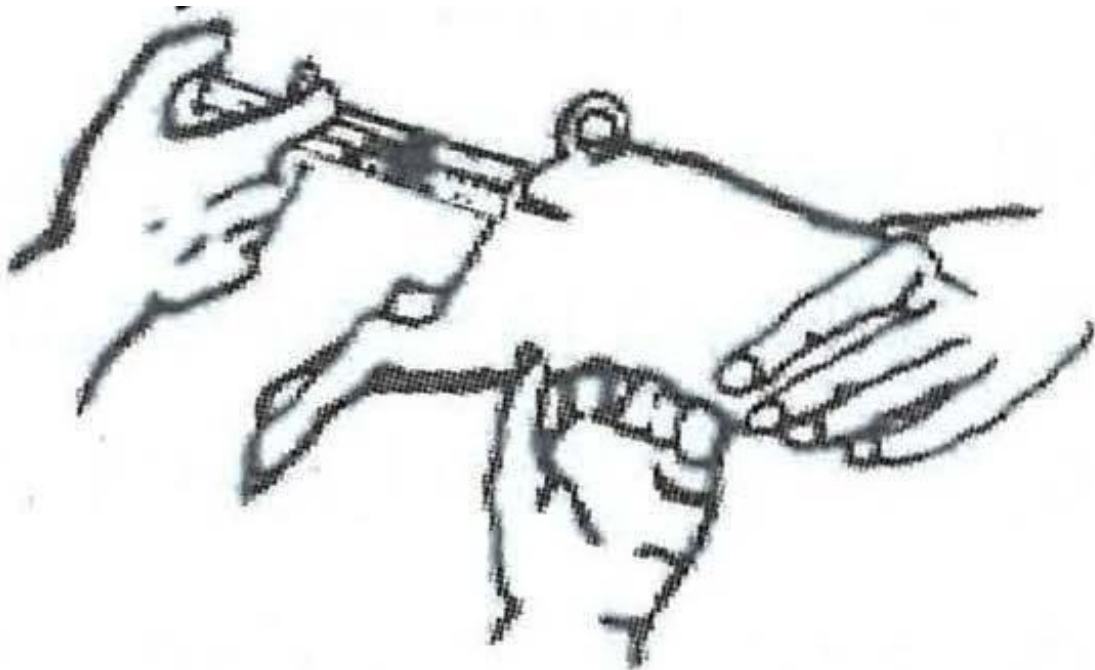
GleptoForte® is for intramuscular use. The preferred site of injection is the ham muscle. Push the needle directly into the ham to approximately a one-half (1/2) inch depth. Avoid injection into a blood vessel. This is best avoided by pulling back slightly on the plunger after the needle is seated in the ham. If properly located, resistance will be offered to this effort. If the plunger is pulled back easily, remove and relocate the needle.



**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<sup>®</sup>, 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<sup>®</sup> (gleptoferron) injection is available in 100 mL and 250 mL multi-dose vials.

**STORAGE:** Store at 20°C - 25°C (68°F - 77°F). Do not freeze.

**100 mL Vial:** Use within 28 days of first puncture and puncture a maximum of seventy-five (75) times with an 18-gauge needle or five (5) times with a dosage delivery device. If using a needle larger than 18-gauge or a draw-off spike larger than 4-gauge, discard any remaining product immediately after use.

**250 mL Vial:** Use within 28 days of first puncture and puncture a maximum of one hundred (100) times with an 18-gauge needle or five (5) times with a dosage delivery device. If using a needle larger than 18-gauge or a draw-off spike larger than 4-gauge, discard any remaining product immediately after use.

**Manufactured for:**

Ceva Animal Health, LLC, Lenexa, KS 66215  
1-800-999-0297

GleptoForte® is a registered trademark of Ceva Santé Animale

**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**

Approved by FDA under ANADA # 200-587

Net Contents: 100mL

**INDICATIONS:** For the prevention and treatment of Baby Pig Anemia due to iron deficiency.

**DOSAGE AND ADMINISTRATION:**  
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.  
Read package insert carefully before use.

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

**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 seventy-five (75) times with an 18-gauge needle or five (5) times with a dosage delivery device. If using a needle larger than 18-gauge or a draw-off spike larger than 4-gauge, discard any remaining product immediately after use.

**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**

Approved by FDA under ANADA # 200-587  
Net Contents: 100mL

Multi-dose, sterile vial.  
Each 1 mL contains 200 mg of elemental iron as gleptoferron. Contains 0.5% phenol as a preservative.

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

**MANUFACTURED FOR:**  
Ceva Animal Health, LLC, Lenexa, KS 66215  
1-800-999-0297

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E59410B 20-K1-v1

**Principal Display Panel - 250 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**

Approved by FDA under ANADA # 200-587

Net Contents: 250mL

<p><b>INDICATIONS:</b> For the prevention and treatment of Baby Pig Anemia due to iron deficiency.</p> <p><b>DOSAGE AND ADMINISTRATION:</b> 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. Read package insert carefully before use.</p> <p><b>WITHDRAWAL PERIODS:</b> No withdrawal period is required when used according to labeling.</p> <p><b>STORAGE:</b> 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 one hundred (100) times with an 18-gauge needle or five (5) times with a dosage delivery device. If using a needle larger than 18-gauge or a draw-off spike larger than 4-gauge, discard any remaining product immediately after use.</p>		<p>Multi-dose, sterile vial. Each 1 mL contains 200 mg of elemental iron as gleptoferron. Contains 0.5% phenol as a preservative.</p> <p><b>NOTICE:</b> Organic iron preparations injected intramuscularly into pigs beyond 4 weeks of age may cause staining of the muscle tissue.</p> <p>Manufactured in Brazil</p> <p><b>MANUFACTURED FOR:</b> Ceva Animal Health, LLC, Lenexa, KS 66215 1-800-999-0297</p>  <p>E59430B 20-T1-v1</p>
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## GLEPTOFORTE

gleptoferron injection

### Product Information

<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:13744-525
<b>Route of Administration</b>	INTRAMUSCULAR		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLEPTOFERRON (UNII: 898723IQHQ) (GLEPTOFERRON - UNII:898723IQHQ)	GLEPTOFERRON	200 mg in 1 mL

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13744-525-01	100 mL in 1 VIAL, MULTI-DOSE		
2	NDC:13744-525-02	250 mL in 1 VIAL, MULTI-DOSE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200587	09/13/2016	

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

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

Revised: 12/2021

Ceva Sante Animale