

A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{NATURE/TYPE}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GLEPTOSIL® 200 mg/ml solution for Injection
Gleptoferron complex

® GLEPTOSIL is a registered Trade Mark of Ceva Animal Health

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each mL contains 200 mg Iron and 5 mg Phenol as a preservative.

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Neonatal pigs

6. INDICATION(S)

For the prevention and treatment of iron deficiency anaemia in neonatal pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Swap the septum before use.

Administration by deep intramuscular Injection into the hind limb, observing aseptic technique.

Prevention of Iron deficiency anaemia: 1 mL within the first three days of life.

Treatment of Iron deficiency anaemia: 1 mL when signs of Iron deficiency appear, normally within the first three weeks of life.

8. WITHDRAWAL PERIOD

Meat and offal: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: Care should be taken to avoid accidental self injection. In the event of accidental self injection, seek medical advice. Wash hands after use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

Protect from light.

Do not open sachet until Gleptosil® is required for use

Avoid the introduction of contamination during use.

Following withdrawal of the first dose, use product within 28 days. Rinse containers thoroughly with water. See package leaflet for full disposal advice.

Keep container in the outer carton

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

UK: Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

IE: Ceva Santé Animale
10, av. de La Ballastière
33500 Libourne
France

16. MARKETING AUTHORISATION NUMBERS

UK: Vm 15052/4079 POM - VPS
IE: VPA 10815/027/001 L.M

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

PARTICULARS TO APPEAR ON THE LABEL
{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GLEPTOSIL® 200 mg/ml solution for Injection
Gleptoferron complex containing 200 mg/ml elemental Iron

® GLEPTOSIL is a registered Trade Mark of Ceva Animal Health Ltd

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each mL contains 200 mg Iron and 5 mg Phenol as a preservative.

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Neonatal pigs

6. INDICATION(S)

For the prevention and treatment of iron deficiency anaemia in neonatal pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By deep intramuscular Injection into the hind limb, observing aseptic technique

8. WITHDRAWAL PERIOD

Meat and offal: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: Care should be taken to avoid accidental self Injection. In the event of accidental self injection, seek medical advice. Wash hands after use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

Protect from light.

Following withdrawal of the first dose, use product within 28 days.

Read the package leaflet before use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

See package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

PACKAGE LEAFLET FOR:

GLEPTOSIL, 200 mg/ml, solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

UK : Ceva Animal Health Ltd,
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

IE: Ceva Santé Animale
10, av. de La Ballastière
33500 Libourne
France

Manufacturers responsible for batch release:

IZO
S.S. 234, Km28,200
27013 Chignolo Po (PV), Italy

Ceva Santé Animale
10 av. de la Ballastière
33500 Libourne, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GLEPTOSIL 200 mg/ml solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Solution for injection

Gleptosil is a colloidal solution of gleptoferron, a macromolecular complex containing iron (200 mg/ml) in a readily utilisable form, and 5 mg/ml Phenol as a preservative.

4. INDICATION(S)

Gleptosil is indicated for the prevention and treatment of iron deficiency anaemia in piglets. Piglets born and reared under intensive conditions are deficient in iron and rapidly become anaemic. Unless they receive supplemental iron early in life they are prone to suffer decreased vitality, poorer growth rates and increased susceptibility to disease.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None.

7. TARGET SPECIES

Neonatal pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Prevention: 1 ml (200 mg iron) per piglet injected within the first three days of life.

Treatment: 1 ml (200 mg iron) per piglet injected at the onset of clinical anaemia, normally within the first three weeks of life.

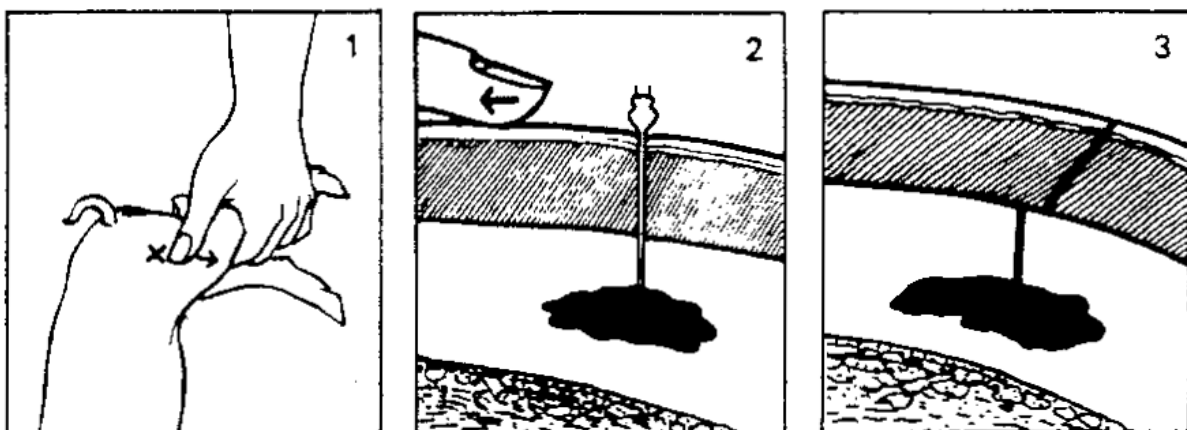
9. ADVICE ON CORRECT ADMINISTRATION

Gleptosil is recommended for administration by intramuscular injection deep into the hind limb. The site of injection should be clean, ideally swabbed with cotton wool soaked in surgical spirit. Excess spirit should be removed before injecting. The syringe and needles should be sterilised by boiling before use and the rubber seal (septum) of the vial should be swabbed with cotton wool soaked in surgical spirit.

For 100 & 250 ml multilayer plastic vials: as the vial cannot be broached more than 20 times, use of automatic syringe equipment is recommended.

For 100 ml collapsible vial: use of automatic syringe equipment only.

The injection site is on the hind limb mid-way between the stifle joint and the base of the tail. Pull the skin and underlying tissue aside with the thumb. Insert the needle at right angles to the skin and slowly inject the 1 ml dose. Pause after injecting the dose and release the skin before withdrawing the needle. Wipe the needle with cotton wool and spirit before injecting the next piglet. A hypodermic needle of size 1/2 Inch No 20 SWG is recommended.



10. WITHDRAWAL PERIOD

Meat and offal: zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the container in the outer carton.

Do not open sachet until Gleptosil is required for use (for collapsible bottle presentation).

Do not store above 25°C.

Protect from light.

Following withdrawal of the first dose, use the product within 28 days.

Write the discard date in the box provided on the label.

Rinse containers thoroughly with water.

Dispose of the rinsing in slurry or dirty water.

Dispose of rinsed containers in the farm refuse.

Avoid the introduction of contamination during use.

Should any apparent growth or discolouration occur, the product should be discarded.

12. SPECIAL WARNING(S)

Care should be taken to avoid accidental self injection.

In the event of accidental self-injection seek medical advice. Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Available in:

100 ml low density polyethylene bottle in a sachet.

100 & 250 ml translucent multi layer plastic vial

Not all pack sizes may be marketed.

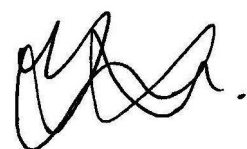
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Approved: 06 October 2022