

GLEPTOSIL®



The power of the original gleptoferron in **a lightweight vial**



Gleptosil
now in **CLAS VIAL**



DIN 02245952

Gleptosil®
Iron Dextran Complex
Injection 200 mg/mL
Injection de complexe de
fer-dextran à 200 mg/mL

Veterinary Use Only
Usage vétérinaire seulement

Warnings: Keep out of reach of children.
Mises en garde: Garder hors de la portée
des enfants.

Sterile/Stérile
Net 250 mL



Each 1 mL contains Active Ingredient - 200 mg
Iron (as Gleptoferron (Iron Dextran Complex))
Preservative: 0.5 % w/v phenol.

Indication: Gleptosil® (Iron 200 mg/mL Solution for Injection) is a haematinic for the prevention and treatment of iron deficiency anaemia in piglets.

STORAGE: DO NOT STORE ABOVE 25°C. PROTECT FROM FREEZING. USE WITHIN 28 DAYS AFTER RECONSTITUTION OF THE VIAL.

Dosage and Administration: 1 mL (200 mg) per piglet by deep intramuscular injection. For complete product information refer to package insert.

29462-31002033

**farmers
depot**



Gleptosil
now in **CLAS VIAL**



SHATTER RESISTANT

Reduces risk of breakage and injury, increases animal and human safety, avoids extra costs from wasted product and helps prevent ground contamination.



EASIER HANDLING

Unique design and light weight maximize ergonomic performance in farm conditions and groove grip improves handling and user safety.



ECO-FRIENDLY

The overall impact on the environment from CLAS vials is 33% less than for glass vials.¹



GREAT PRODUCT STABILITY

Its high-tech triple-layers make the vial's wall impervious to water and oxygen and ensure excellent product protection and stability.



Thanks to its lightweight, shock resistant, and ergonomic shape,
CLAS is preferred by 99% of users over glass vials²

THE IMPORTANCE OF **IRON SUPPLEMENTATION**



Piglets are born with a limited iron store and so they need supplementation with a quality iron source. Iron is needed to synthesize hemoglobin and is required to prevent anemia and for proper immune function.

Neonatal piglets require iron supplementation.

Gleptoferron is a macromolecular complex of beta-ferric oxyhydroxide and dextran glucoheptonic acid with rapid and almost complete absorption after administration. It has an excellent safety profile for young piglets.³


PHARMACOKINETICS OF GLEPTOFERRON (GLEPTOSIL)

A KEY FACTOR IN ITS HIGH EFFICACY⁴


Absorption of iron following administration is an important efficacy parameter for iron products. A study comparing the absorption and the efficacy of **gleptoferron (Gleptosil®)** and iron dextran was conducted, and the results were published in a peer-reviewed journal:

Materials and methods

- **A total of 32 piglets** from four litters were included in this study. On the second day of life, eight piglets were randomly selected per litter and injected with one of two sources of iron, **GLF (Gleptosil®)** or DXT (iron dextran) — i.e., four piglets per treatment group in each litter.
- Serum iron concentrations and other parameters were analysed and the following pharmacokinetic parameters were calculated: the peak concentration (C_{max}), time to peak concentration (T_{max}), half-life ($T_{1/2}$) and extent of absorption (AUC).
- **The absorption and the bioavailability of iron** were significantly higher with GLF than DXT ($p < 0.001$).

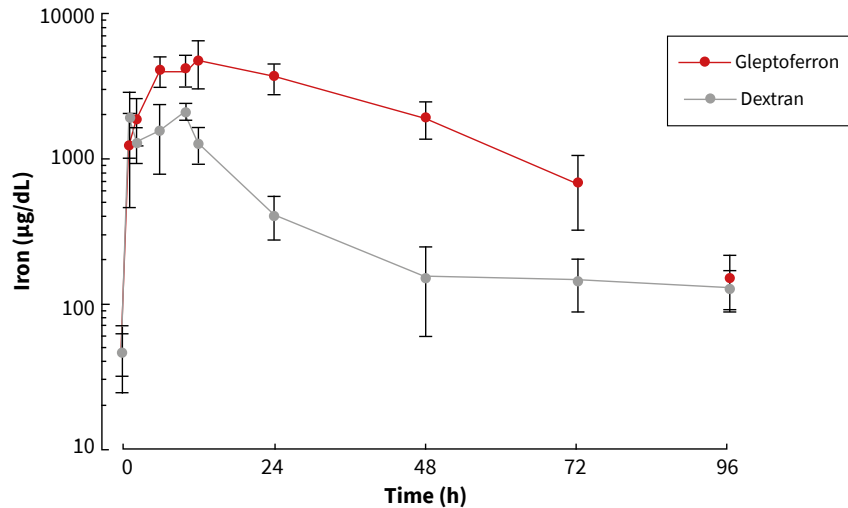


Under the conditions of this study, the pharmacokinetic profiles of the two iron products were different. **The absorption and relative availability of GLP was significantly higher**



Results

Iron mean concentration-time profiles (\pm standard error) of serum iron after single intramuscular administration of 200 mg per piglet as gleptoferron or iron dextran was analysed.



Mean pharmacokinetic parameters of serum iron after a single intramuscular administration of 200 mg iron per piglet as gleptoferron or iron dextran.

Pharmacokinetic parameter	GLF	DXT
C _{max} (µg/dL)	4695	2118
T _{max} (h)	12.0	10.0
T _½ (h)	17.3	10.7
AUC _{0-96h} (h · µg/dL)	197.55	43.03
Relative bioavailability*	4.6	1



* Relative bioavailability of GLF = AUC_{0-96h} GLF/AUC_{0-96h} DXT. GLF = gleptoferron; DXT = iron dextran; C_{max} = maximum serum concentration; T_{max} = time to reach C_{max}; T_½ = elimination half-life; AUC_{0-96h} = area under the curve.

FIELD EVALUATION OF HEMOGLOBIN (HB) LEVELS IN PIGLETS AT WEANING ON EUROPEAN FARMS⁵

2,349 piglets evaluated



A survey was conducted
in 8 European countries

The hemoglobin (Hb) levels of piglets at weaning on European farms and the effect of the type of iron product used was assessed in field studies, as presented below.

The **aim** of this study was to assess the prevalence of iron deficiency anemia (IDA) in selected EU countries and to identify risk factor associated with it.

Materials and methods

- Eight countries were included in the survey and 2,349 large, medium, and small piglets were assessed:

Austria n= **90**

Denmark n= **300**

France n= **360**

Belgium n= **300**

The Netherlands n= **291**

Portugal n= **288**

The Czech Republic n= **510**

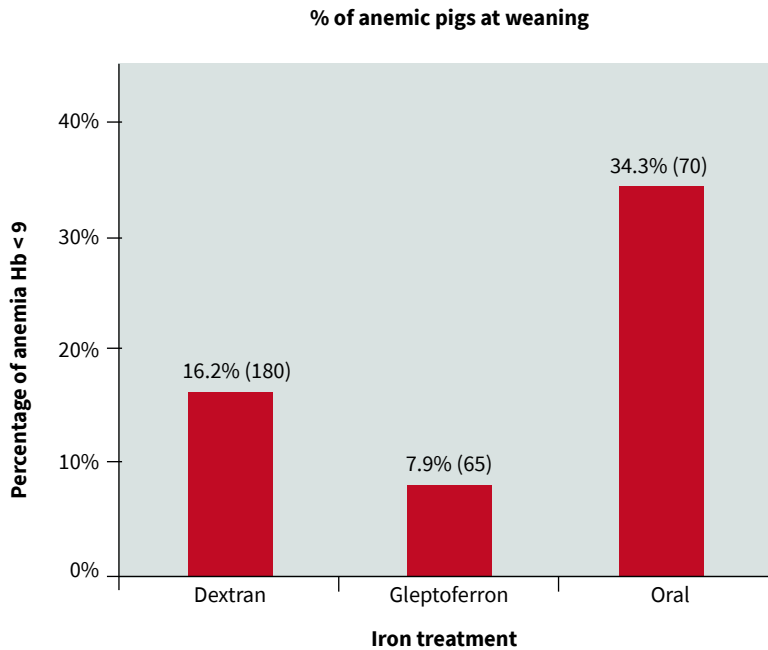
Germany n= **210**

- Litters from sows with different parity numbers were randomly selected (10 litters/30 piglets per farm).
- Their Hb levels were measured using Hemocue® Hb 201 + and the piglets were classified as follows:
 - Hb levels < 90 g/L = anemic
 - Hb levels ≥ 90 g/L and < 110 g/L = suboptimal
 - Hb levels ≥ 110 g/L = are optimal

Risk factors for iron deficiency anemia included
the use of oral iron, **low sow parity, and large piglet size.**

Results

- In total, 14.7% of piglets assessed were anemic and there were significant differences between the countries included in this survey ($p < 0.0001$).
- The percentage of anemic piglets observed also significantly varied according to whether the dextran, gleptoferron, or oral form of iron was used, resulting in 16.2%, 7.9%, and 34.3%, respectively ($p < 0.0001$).
- Gleptoferron based products provided the best results in terms of risk of IDA at weaning, only 7.9% of piglets being anemic in this survey.



GLEPTOSIL®



H I G H P E R F O R M A N C E I R O N



1. Life cycle analysis 2016, Data on file. 2. Data on file. 3. Summary of Product Characteristics. Product Information Database. (n.d.). Retrieved June 26 2020, from <https://www.vmd.defra.gov.uk/ProductInformationDatabase/Default.aspx> 4. Morales J, Manso M, Martín-Jiménez T, Karembe H, Sperling D. Comparison of the pharmacokinetics and efficacy of two different iron supplementation products in suckling piglets. J Swine Health Prod. 2018;26(4):200-207. 5. Sperling D, Karembe H, Suarez P, Guerra N, Lopez A. Field evaluation of Hemoglobin (Hb) levels in piglets at weaning on European farms. Ceva Internal data: Cev-015-2020.

This document contains information on a veterinary biological product sold in several different countries and areas where it may be marketed under different trade names and pursuant to different regulatory approvals. Accordingly, Ceva gives no guarantee that the details presented are correct with respect to all locations. In addition, the safety and efficacy data may be different depending on local regulations. Please consult your veterinarian for further information.