IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Gleptoferron 200 mg/ml Solution for Injection

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Gleptoferron 200 mg/ml Solution for Injection
Active substance(s)	Iron (as Gleptoferron Complex)
Applicant	Labiana Life Sciences S.A. C/Venus 26 - Terrassa 08228 (Barcelona) Spain
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of Authorisation	23rd December 2016
Target species	Porcine
Indication for use	For the prevention and treatment of iron deficiency anaemia.
ATCvet code	QB03AC91

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.

It has been shown that the product can be safely used in the target species; the possible reactions that may be observed are indicated in the SPC.

The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 200 mg/ml iron (as gleptoferron complex) and the excipients phenol, sodium chloride and water for injections.
The container/closure system is 100 ml and 200 ml low density polyethylene (LDPE) or high density polyethylene (HDPE) collapsible bottles with chlorobutyl rubber closures and aluminium ring seals. The LDPE bottles are sealed in a polyester/polyethylene laminate sachet.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is iron (as gleptoferron complex), an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on Intermediate Products

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product has been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This is a generic application according to Article 13 and has been submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended. The product includes iron (gleptoferron complex) as active substance.

The reference product cited in this generic application is Gleptosil 200 mg/ml Solución inyectable as authorised in Spain (2454 ESP), the marketing authorisation of which is held by the applicant. Consequently, the formulations are identical (identical active substances and excipients as well as physicochemical properties) and it can be accepted that the product meets guideline requirements to justify the omission of *in-vivo* bioequivalence studies. The candidate and reference formulations may be considered bioequivalent.

Warnings and precautions as listed on the product literature are in line with those of the reference product and are considered adequate to ensure safety of the product to users, the environment and consumers of animals administered the product.

III.A Safety Testing

Pharmacological Studies

Given that the candidate formulation is identical (identical active substances and excipients as well as physicochemical properties) to the reference product, the omission of pre-clinical pharmacological study data was accepted and the pharmacological aspects of the reference product may be extrapolated to the generic product.

Toxicological Studies

Given that the candidate formulation is identical (identical active substances and excipients as well as physicochemical properties) to the reference product, the omission of toxicological study data was accepted and the toxicological profile of the reference product may be extrapolated to the generic product.

User Safety

The applicant provided a user safety assessment. Given that the candidate formulation is identical (identical active substances and excipients as well as physicochemical properties) to the reference product and the product will be administered to the same target species using the same route of administration at the same posology as approved for the reference product, no difference in risk for the user is to be expected between the candidate and reference product formulations.

It was concluded that the product will be safe for the user when handled, administered, stored and disposed of in accordance with the recommendations included in the SPC.

Warnings and precautions as listed on the product literature are considered adequate to ensure safety to users of the product.

Environmental Risk Assessment

Phase I
The environmental risk assessment can stop in Phase I because the product includes a natural substance already present in the environment and use of the product will not significantly alter the concentration or distribution of iron in the environment.

It was concluded that the product will be safe for the environment when the product is stored, handled, administered and disposed of in accordance with the recommendations included in the proposed SPC.

III.B Residues Documentation

Residue Studies

No residue depletion studies were conducted because the product is qualitatively and quantitatively identical to the reference product and therefore the absorption, distribution, metabolism, and excretion of the product are expected to be the same as for the reference product.

Further, the product will be administered to the same target species using the same route of administration at the same posology as approved for the reference product.

Consequently, the omission of residue study data was accepted.

MRLs

Gleptoferron is synonymous with dextran-glucoheptanate complexes. Both iron dextran and iron glucoheptanate are included in table 1 of Commission Regulation (EU) No. 37/2010 (no MRL required).

Withdrawal Periods

The withdrawal period (zero days) is the same as that approved for the reference product. As the candidate formulation is identical (identical active substances and excipients as well as physicochemical properties) to the reference product and is to be administered to the same target species using the same route of administration at the same posology as approved for the reference product and given the fact that the product is only intended for administration to neonatal piglets, it was accepted that the withdrawal period of zero days is adequate to ensure consumer safety.

IV CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The candidate formulation is identical (identical active substances and excipients as well as physicochemical properties) to the reference product and will be administered to the same target species using the same route of administration at the same posology as approved for the reference product. Consequently, the omission of target animal tolerance data was accepted and the safety profile of the reference product for the target species may be extrapolated to the generic product.

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

The candidate formulation is identical (identical active substances and excipients as well as physicochemical properties) to the reference product and will be administered to the same target species using the same route of administration at the same posology as approved for the reference product. Consequently, the omission of clinical study data and field trial data was accepted and the efficacy profile of the reference product may be extrapolated to the generic product.

The efficacy claims for this product are equivalent to those of the reference product. The efficacy of the product is expected to be the same as for the reference product when handled and administered in accordance with the recommendations included in the SPC.

V OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA website.

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Changes:
None.