IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Fixplan 200 IU/ml lyophilisate and solvent for solution for injection

PRODUCT SUMMARY

EU Procedure number	IE/V/0448/001/DC
Name, strength and pharmaceutical form	Fixplan 200 IU/ml lyophilisate and solvent for solution for injection
Active substances(s)	Gonadotrophin, equine serum, for veterinary use
Applicant	Syn Vet-Pharma Ireland Limited, Business Service Group, 7A Durands Court, 45 Parnell Street, Waterford, X91 P381, Ireland
Legal basis of application	Generic application (Article 13(1) of Directive No 2001/82/EC)
Date of Authorisation	10/02/2021
Target species	Cattle, pigs, sheep
Indication for use	To stimulate the development of the ovarian follicle in the female. Cows: Treatment of anoestrus/ induction of oestrus, induction of superovulation and increase in fertility rates after progestagen pre-treatment. Ewes: Increase in fertility rates after progestagen pre-treatment. Sows: Treatment of anoestrus post-weaning/ induction of oestrus.
ATCvet code	QG03GA03
Concerned Member States	BE, DE, ES, FR, HU, IT, NL, PL, PT, UK(NI)

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 product literature accurately reflects the type and incidence of adverse effects which might be expected.
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 IU/ml of equine serum gonadotrophin and the excipients mannitol, disodium phosphate, sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, and water for injections.
The container/closure system consists of the lyophilisate packaged in an 8 ml type I colourless glass vial and the solvent packaged in a 30 ml type II colourless glass vial, with grey bromobutyl rubber stoppers with flip-off aluminium seals and polypropylene caps.

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 equine serum gonadotrophin for veterinary use, an established substance described in the European Pharmacopoeia. 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

Compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control on Intermediate Products

Not applicable.

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 application was submitted in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC (a "generic" veterinary medicinal product). The reference veterinary medicinal product is Folligon PMSG 200 IU/ml lyophilisate and solvent for solution for injection containing equine serum gonadotrophin as active substance.

Pharmacological Studies

An exemption from the requirement for conducting bioequivalence studies was justified in accordance with current guidance, section 7.1(b) of EMA/CVMP/016/00-Rev.3 (Guideline on the conduct of bioequivalence studies for veterinary medicinal products):

"for products intended for intramuscular, subcutaneous or systemically acting topical administration, bioequivalence studies are not required in cases when the product is of the same type of solution, contains the same concentration of the active substance and comparable excipients in similar amounts as the reference veterinary medicinal product, if it can be adequately justified that the difference(s) in the excipient(s)and/or their concentration have no influence on the rate and/or extent of absorption of the active substance;"

Based on the information provided, bioequivalence with the reference formulation has been accepted. Consequently, results of pharmacological tests are not required.

Toxicological Studies

As this is a generic application under Article 13(1) and as bioequivalence with a reference product is accepted, results of toxicological tests are not required.

The safety aspects of this product are expected to be the same to those of the reference product.

Warnings and precautions as listed on the product literature are broadly in line with those of the reference product.

User Safety

The applicant has provided a user safety assessment which shows that the risk to the user associated with this product is the same to that of the reference product. The proposed user safety statements are broadly in line with those of the reference product and are acceptable.

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

Environmental Risk Assessment

The Applicant has provided an environmental impact assessment as required.

Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

Consumer safety

As this is a generic application under Article 13(1) and as bioequivalence with a reference product is accepted and the formulation of the generic product can be accepted as being sufficiently similar to the reference product, studies investigating the depletion of residues are not required.

The active substance gonadotrophin releasing hormone is included in table 1 of the Annex to Commission Regulation (EU) No. 37/2010 as 'no MRL required'.

The proposed withdrawal periods are identical to those approved for the reference product in the RMS and are considered adequate to ensure consumer safety.

IV. CLINICAL ASSESSMENT

As this is a generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended, and as bioequivalence with a reference product is accepted, efficacy studies are not required.

The efficacy claims for this product are expected to be equivalent to those of the reference product. In addition, it is considered that the risk to the target species will be similar for both the test and the reference products. The product literature accurately reflects the type and incidence of adverse effects which might be expected.

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.