IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Nandrosol 25 mg/ml solution for injection for dogs and cats

PRODUCT SUMMARY

EU Procedure number	IE/V/0466/001/DC
Name, strength and pharmaceutical form	Nandrosol 25 mg/ml solution for injection for dogs and cats
Active substances(s)	Nandrolone laurate
Applicant	CP-Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany
Legal basis of application	Generic application (Article 13(1) of Directive No 2001/82/EC)
Date of Authorisation	31/07/2019
Target species	Cats, Dogs
Indication for use	Indicated for use in dogs and cats as an adjunctive treatment for conditions in which anabolic therapy is considered to be beneficial.
ATCvet code	QA14AB01
Concerned Member States	DE

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 slight reactions observed are indicated in the SPC.
The product is safe for the user, 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 25 mg/ml nandrolone laurate as the active substance and the excipients benzyl alcohol and arachis oil, refined. The container/closure system consists of clear glass vials of Type I (5 ml presentation) or Type II (10 and 20 ml presentations) which are closed with coated bromobutyl rubber stoppers and aluminium 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 nandrolone laurate, an established substance described in the British Veterinary 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
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
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)

The application for Nandrosol vet. 25 mg/ml solution for injection for dogs and cats containing nandrolone laurate as active substance was submitted in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC, as amended, i.e., an application for a generic veterinary medicinal product. The reference veterinary medicinal product is Laurabolin 25 mg/ml solution for injection – containing 25 mg/ml nandrolone laurate – as registered in Ireland (VPA 10996/002/001 – Intervet Ireland Limited) since 1/10/1987.

III.A Safety Testing
Pharmacological Studies
It was claimed that the product has the same qualitative and quantitative composition in terms of active ingredient and the same excipients in similar amount to the reference veterinary medicinal product, Laurabolin. Both products are solutions for injection and they are to be used in dogs and cats, for the same indications, at the same dose and using the same administration method.
The claim that Nandrosol can be considered the same as the reference product is based on a comparison of the qualitative and quantitative composition of both products, including a comparison of physicochemical properties. Based on these data, the applicant claimed that an exemption from the requirement to conduct an *in vivo* bioequivalence study is justified in accordance with current guidance, EMA/CVMP/016/00-Rev2 ("Guideline on the conduct of bioequivalence studies for veterinary medicinal products"), Chapter 7.1 (b):

For product 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 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.

Given that bioequivalence is claimed, the applicant is not required to provide the results of safety and residue tests or of pre-clinical and clinical trials.

Based on the argumentation and the comparative data presented, it was accepted that the test product can be considered bioequivalent to the reference product.

Toxicological Studies
As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC, as amended, and as bioequivalence with a reference product is accepted, results of toxicological tests are not required.
The safety aspects of this product are accepted as being identical 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 in compliance with the relevant guideline which shows that the risk to the user associated with this product is identical to that of the reference product. The proposed user safety statements are similar to those of the reference product and are considered acceptable.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product:

- In the event of accidental self-injection, transient painful, local reactions may occur. Avoid accidental self-injection. In the case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.
- This product contains benzyl alcohol and can cause skin irritation. Avoid contact with skin. In the case of contact with skin, wash with soap and water. If irritation persists, seek medical advice. Wash hands after use.
- The product can cause eye irritation. Avoid contact with eyes. If the product comes into contact with the eyes, rinse the eyes immediately with plenty of water and seek medical attention if irritation persists.
- Virilisation of the foetus may occur if pregnant women are exposed to the product. Therefore, the veterinary medicinal product should not be administered by pregnant women or women trying to conceive.
- This product may cause hypersensitivity reactions. People with known hypersensitivity to nandrolone, benzyl alcohol or peanut oil should avoid contact with the veterinary medicinal product. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Environmental Risk Assessment

Phase I
An environmental risk assessment was provided. The environmental risk assessment (ERA) can stop in Phase I because the product is intended for use in non-food animals only.
Conclusion
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.

IV. CLINICAL ASSESSMENT

See **Part III.A**
As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC, as amended, and bioequivalence with a reference product is accepted, efficacy studies are not required. The efficacy claims for this product can be assumed 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 nature 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.