IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Vulketan 2.5 mg/g gel for horses

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

PRODUCT SUMMARY

EU Procedure number	IE/V/0265/001/DC
Name, strength and pharmaceutical form	Vulketan 2.5 mg/g gel for horses
Active substance(s)	Ketanserin tartrate
Marketing Authorisation Holder	AUDEVARD 42/46 Rue Mederic 92110 Clichy France
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	22nd June 2011
Target species	Horses
Indication for use	To encourage wound healing and prevention of the formation of hyper-granulation tissue in horses.
ATCvet code	QD03AX90

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 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 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 3.45 mg/g Ketanserin tartrate (equivalent to 2.5 mg/g ketanserin) and the excipients propylene glycol, hypromellose, methyl parahydroxybenzoate, propyl parahydroxybenzoate and water for injections.

The product is packaged in 75 g aluminium tubes with internal coating and a white HDPE screw cap.

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 on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is Ketanserin tartrate, 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 have 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 have been provided.
Batch analytical data from the proposed production sites have 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 have 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

None.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

This application has been submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended (that is, a generic application). The reference product is Vulketan 2.5 mg/g wound gel (VPA 10545/022/001) which has been authorised in the RMS for not less than 10 years.

Given that the formulations of Vulketan vet 2.5 mg/g gel for horses and Vulketan 2.5 mg/g wound gel are considered the same, it can be accepted that the bioavailability of ketanserin following administration will be similar for both products. In accordance with paragraph 4(c) of the current bioequivalence guideline, such products can be considered bioequivalent and may be exempt from the need to conduct

bioequivalence studies. Given that bioequivalence with the reference product is assumed, pharmacological or toxicological data have not been provided. It is accepted that the safety profile of the generic product is the same as that of the reference product.

User Safety

The Applicant provided a user safety assessment conducted in accordance with current guidance. The low inherent toxicity of the product and the potential exposure scenarios identified by the applicant demonstrate that the risk to the user is acceptable when the product is used in accordance with label recommendations. It is accepted that the user safety aspects of this product are identical to the reference product. As a precautionary measure, the following user safety statements have been included in the product literature:

-Wear disposable gloves when handling the product. Wash hands thoroughly after use. In case of accidental eye contact with the veterinary medicinal product, rinse with water.

-In case of accidental spillage onto skin, wash off immediately with soap and water.

-In case of ingestion of the product by a child, seek medical attention immediately and show the package leaflet to the doctor.

Environmental Risk Assessment

The Applicant provided a first phase environmental risk assessment for the product. In accordance with the relevant guideline, the ERA concluded at Phase I on the basis that the product will be used to treat individual animals. No further assessment is required.

Residues

The 'zero day' withdrawal period for this product is in line with the authorised withdrawal period of the reference product in the RMS and is accepted.

IV. CLINICAL ASSESSMENT

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The indications and posology proposed for Vulketan vet 2.5 mg/g gel for horses are identical to that approved for the reference product and are as follows:

Indication: To encourage wound healing
Prevention of the formation of hyper-granulation tissue.

Dosage:Clean the wound thoroughly with clean potable water and then apply theproduct, after bleeding has ceased, to the entire surface of the wound and the edges twice daily.
Washing with clean warm water is recommended before every treatment. Bandaging of the wound and restraint of the limb are not necessary.

Tolerance data specific to Vulketan vet 2.5 mg/g gel for horses have not been presented. However, it is accepted that this product will not present any greater risk to the target species than the minimal risk posed by the reference product

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