Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Butaleve 1 g Oral Powder for Horses and Ponies

Date Created: July 2019

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Butaleve 1 g Oral Powder for Horses and Ponies
Applicant	Dechra Limited Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW
Active substance	Phenylbutazone
ATC Vetcode	QM01AA01
Target species	Horses and ponies
Indication for use	For the treatment of musculoskeletal disorders in horses and ponies where the anti-inflammatory and analgesic properties of phenylbutazone can offer relief. Examples of conditions normally considered suitable for treatment with phenylbutazone include lameness associated with osteoarthritic conditions, acute and chronic laminitis, bursitis and carpitis, and in the reduction of post-surgical soft tissue reaction.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

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As the product was refused a marketing authorisation, a Summary of Product Characteristics was not approved for this product.

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed Consent application in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	12th July 2019

I. SCIENTIFIC OVERVIEW

For applications based on informed consent to another authorisation:

The quality, safety and efficacy aspects of this product is identical to Equipalazone 1 g oral Paste. The initial application for Equipalazone 1 g Oral Paste was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

II 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 of the product is favourable.

MODULE 4

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 Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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