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

Skylocalm 3.6 mg Film-coated Tablets for Dogs
Skylocalm 5.4 mg Film-coated Tablets for Dogs
Skylocalm 16 mg Film-coated Tablets for Dogs

Date Created: January 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Skylocalm 3.6 mg Film-coated Tablets for Dogs Skylocalm 5.4 mg Film-coated Tablets for Dogs Skylocalm 16 mg Film-coated Tablets for Dogs
Applicant	Zoetis UK Limited
Active substance	Oclacitinib
ATC Vetcode	QD11AH90
Target species	Dogs
Indication for use	Treatment of pruritus associated with allergic dermatitis in dogs. Treatment of clinical manifestations of atopic dermatitis in dogs.

MODULE 2

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

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed Consent application in accordance with Article 13c of Directive 2001/82/EC as amended
Date of conclusion of the procedure	10/01/2023

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of these products are identical to Apoquel Film-coated Tablet for Dogs (3.6mg, 5.4mg and 16mg).

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(s) 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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