Prolevare 5.4 mg - Film-coated tablet

Authorised

- Oclacitinib maleate

Product identification

Medicine name:
Prolevare 5.4 mg - Film-coated tablet

Active substance:
Oclacitinib maleate

Target species:
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Oclacitinib maleate
7.26 milligram(s) / 1.00 Tablet

Pharmaceutical form:
Film-coated tablet

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QD11AH90

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Austria , Belgium , Bulgaria , Croatia , Cyprus , Czechia , Denmark , Estonia , Finland , France , Germany , Greece , Hungary , Iceland , Ireland , Italy , Latvia , Liechtenstein , Lithuania , Luxembourg , Malta , Netherlands , Norway , Poland , Portugal , Romania , Slovakia , Slovenia , Spain , Sweden , United Kingdom (Northern Ireland)

Package description:
Packaging:Blister (Alu/PVC/Aclar), Package_size:100 tablets
Packaging:Blister (PVC/PVDC/Alu), Package_size:100 tablets

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Informed Consent application (Article 21 of Regulation (EU) 2019/6)

Marketing authorisation holder:
Zoetis Belgium SA

Marketing authorisation date:
24/04/2023

Manufacturing sites for batch release:
Zoetis Belgium
Pfizer Italia S.r.l.

Responsible authority:
European Commission

Authorisation number:
This information is not available for this product.

Date of authorisation status change:
24/04/2023

Informed consent reference:
600000004126
600000004127
600000004128
600000035463
600000035464
600000035462

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Combined File of all Documents

English (PDF)
Published on: 28/07/2025
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