

DV8FLEA COMBO XL 402 mg / 361.8 mg spot-on solution for dogs

Authorised

- (S)-Methoprene
- Fipronil

Product identification

Medicine name:

DV8FLEA COMBO XL 402 mg / 361.8 mg spot-on solution for dogs

Active substance:

(S)-Methoprene

Fipronil

Target species:

Dog

Route of administration:

Spot-on use

Product details

Active substance and strength:

(S)-Methoprene

361.80 milligram(s) / 1.00 Pipette

Fipronil
402.00 milligram(s) / 1.00 Pipette

Pharmaceutical form:

Spot-on solution

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QP53AX65

Legal status of supply:

Veterinary medicinal product not subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Ireland

Package description:

A red pipette composed of a heat-formed shell (internal layer PE/EVOH/PE external layer PP/COC/PP) and a film (PET/PE/ALU/PE). Package sizes: 1 x 4.02 ml pipette in carton box

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Hybrid application – bioavailability studies cannot be used to demonstrate bioequivalence (Article 19(1)(b) of Regulation (EU) 2019/6)

Marketing authorisation holder:

Duggan Veterinary Supplies Limited

Marketing authorisation date:

12/04/2024

Manufacturing sites for batch release:

Przedsiębiorstwo Wielobranzowe Vet-Agro Sp. z o.o.

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA10400/005/004

Date of authorisation status change:

12/04/2024

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

Documents

Summary of Product Characteristics