

# Amflee Combo 134 mg/120.6 mg spot-on solution for medium dogs

Authorised

- (S)-Methoprene
- Fipronil

## Product identification

**Medicine name:**

Amflee Combo 134 mg/120.6 mg spot-on solution for medium dogs

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**Active substance:**

(S)-Methoprene

Fipronil

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**Target species:**

Dog

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**Route of administration:**

Spot-on use

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## Product details

**Active substance and strength:**

(S)-Methoprene

120.60 milligram(s) / 1.00 Pipette

Fipronil

134.00 milligram(s) / 1.00 Pipette

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**Pharmaceutical form:**

Spot-on solution

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QP53AX65

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**Legal status of supply:**

Veterinary medicinal product not subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Ireland

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**Available in:**

Ireland

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**Package description:**

White polypropylene single-dose pipette packaged in aluminium foil sachets.

Cardboard box containing 1 pipette.

White polypropylene single-dose pipette packaged in aluminium foil sachets.

Cardboard box containing 3 pipettes.

White polypropylene single-dose pipette packaged in aluminium foil sachets.

Cardboard box containing 6 pipettes.

White polypropylene single-dose pipette packaged in aluminium foil sachets.

Cardboard box containing 30 pipettes.

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Generic application (Article 13(1) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

KRKA tovarna zdravil d.d. Novo mesto

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**Marketing authorisation date:**

6/07/2018

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**Manufacturing sites for batch release:**

KRKA tovarna zdravil d.d. Novo mesto

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**Responsible authority:**

Health Products Regulatory Authority

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**Authorisation number:**

VPA10774/051/002

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**Date of authorisation status change:**

6/07/2018

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**Reference member state:**

Ireland

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**Procedure number:**

IE/V/0451/003

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**Concerned member states:**

Belgium Cyprus Finland Italy Portugal United Kingdom (Northern Ireland)

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To consult adverse reactions on veterinary medicinal products please go to [www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

Summary of Product Characteristics

Combined File of all Documents