

# Amcofen 12.5 mg/125 mg film-coated tablets for dogs weighing at least 5 kg

Authorised

- Milbemycin oxime
- Praziquantel

## Product identification

**Medicine name:**

Amcofen 12.5 mg/125 mg film-coated tablets for dogs weighing at least 5 kg

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**Active substance:**

Milbemycin oxime

Praziquantel

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**Target species:**

Dog

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**Route of administration:**

Oral use

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## Product details

**Active substance and strength:**

Milbemycin oxime

12.50 milligram(s) / 1.00 Tablet

Praziquantel  
125.00 milligram(s) / 1.00 Tablet

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**Pharmaceutical form:**

Film-coated tablet

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

QP54AB51

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Latvia

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**Available in:**

Latvia

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**Package description:**

Blister packs consisting of cold formed aluminium foil which consists of aluminum layer coated with OPA (Oriented Polyamide) film on one side and PVC on the other side and an aluminum sealing foil. Package sizes: Cardboard box with 12 blisters, each blister contains 4 tablets (total 48 tablets).

Blister packs consisting of cold formed aluminium foil which consists of aluminum layer coated with OPA (Oriented Polyamide) film on one side and PVC on the other side and an aluminum sealing foil. Package sizes: Cardboard box with 1 blister of 4 tablets.

Blister packs consisting of cold formed aluminium foil which consists of aluminum layer coated with OPA (Oriented Polyamide) film on one side and PVC on the other side and an aluminum sealing foil. Package sizes: Cardboard box with 1 blister of 2 tablets.

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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:**

23/09/2021

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**Manufacturing sites for batch release:**

KRKA tovarna zdravil d.d. Novo mesto

Krka-Farma d.o.o.

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**Responsible authority:**

Food And Veterinary Service

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**Authorisation number:**

V/DCP/21/0053

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**Date of authorisation status change:**

23/09/2021

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**Reference member state:**

Ireland

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**Procedure number:**

IE/V/0524/004

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**Concerned member states:**

Belgium Bulgaria Croatia Czechia Estonia France Germany Hungary Italy  
Latvia Lithuania Netherlands Poland Portugal Romania Slovakia Slovenia  
Spain United Kingdom (Northern Ireland)

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## Documents

Summary of Product Characteristics

Combined File of all Documents

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