

Clavusan 50 mg + 12.5 mg tablets for dogs and cats

Authorised

- Amoxicillin trihydrate
- Potassium clavulanate

Product identification

Medicine name:

Clavusan 50 mg + 12.5 mg tablets for dogs and cats

Active substance:

Amoxicillin trihydrate

Potassium clavulanate

Target species:

Dog

Cat

Route of administration:

Oral use

Product details

Active substance and strength:

Amoxicillin trihydrate

57.40 milligram(s) / 1.00 Tablet

Potassium clavulanate
14.89 milligram(s) / 1.00 Tablet

Pharmaceutical form:

Tablet

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01CR02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Bulgaria

Package description:

oPA/Alu/PVC - PVC/Alu heat sealed blister containing 10 tablets each. Package sizes:Cardboard box of 250 tablets.

oPA/Alu/PVC - PVC/Alu heat sealed blister containing 10 tablets each. Package sizes:Cardboard box of 100 tablets.

oPA/Alu/PVC - PVC/Alu heat sealed blister containing 10 tablets each. Package sizes:Cardboard box of 50 tablets.

oPA/Alu/PVC - PVC/Alu heat sealed blister containing 10 tablets each. Package sizes:Cardboard box of 30 tablets.

oPA/Alu/PVC - PVC/Alu heat sealed blister containing 10 tablets each. Package sizes:Cardboard box of 10 tablets.

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Hybrid application - change in strength (Article 19(1)(a) of Regulation (EU) 2019/6)

Marketing authorisation holder:

Alfasan Nederland B.V.

Marketing authorisation date:

19/03/2023

Manufacturing sites for batch release:

Lelypharma B.V.

Alfasan Nederland B.V.

Responsible authority:

Bulgarian Food Safety Authority

Authorisation number:

0022-3172

Date of authorisation status change:

19/03/2023

Reference member state:

Ireland

Procedure number:

IE/V/0778/001

Concerned member states:

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

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

Documents

Summary of Product Characteristics

English (PDF)

Published on: 25/09/2024

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Package Leaflet

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Labelling

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