Clavusan 250 mg + 62.5 mg tablets for dogs and cats

Authorised

- Amoxicillin trihydrate
- Potassium clavulanate

Product identification

Medicine name:

Clavusan 250 mg + 62.5 mg tablets for dogs and cats Clavusan 250 mg + 62.5 mg Comprimé Clavusan 250 mg + 62.5 mg Tablet Clavusan 250 mg + 62.5 mg Tablette

Active substance:

Amoxicillin trihydrate Potassium clavulanate

Target species:

Dog Cat

Route of administration:

Oral use

Product details

Active substance and strength:

Amoxicillin trihydrate

287.00 milligram(s) / 1.00 Tablet Potassium clavulanate 74.45 milligram(s) / 1.00 Tablet

Pharmaceutical form:

Tablet

Withdrawal period by route of administration:

Oral use:

Dog • Cat

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01CR02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Belgium

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:

31/03/2023

Manufacturing sites for batch release:

Lelypharma B.V. Alfasan Nederland B.V.

Responsible authority:

Federal Agency For Medicines And Health Products

Authorisation number:

BE-V661247

Date of authorisation status change:

31/03/2023

Reference member state:

Ireland

Procedure number:

IE/V/0778/002

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 <u>www.adrreports.eu/vet</u>

Documents

Summary of Product Characteristics

English (PDF) Published on: 25/09/2024 Download

Package Leaflet

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Labelling

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