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Tramcoat 20 mg film-coated tablets for dogs

Authorised

- Tramadol hydrochloride

Product identification

Medicine name:
Tramcoat 20 mg film-coated tablets for dogs

Active substance:
Tramadol hydrochloride

Target species:
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Tramadol hydrochloride
20.00 milligram(s) / 1.00 Tablet

Pharmaceutical form:
Film-coated tablet

Withdrawal period by route of administration:

Oral use:

- **Dog**

- All relevant tissues. no withdrawal period	Not applicable to dogs.

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN02AX02

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Romania

Package description:
Cardboard box of 1 PVC/PE/PVDC-aluminium blister, containing 10 tablets.
Cardboard box of 2 PVC/PE/PVDC-aluminium blister, containing 10 tablets.
Cardboard box of 3 PVC/PE/PVDC-aluminium blister, containing 10 tablets.
Cardboard box of 4 PVC/PE/PVDC-aluminium blister, containing 10 tablets.
Cardboard box of 5 PVC/PE/PVDC-aluminium blister, containing 10 tablets.
Cardboard box of 6 PVC/PE/PVDC-aluminium blister, containing 10 tablets.
Cardboard box of 7 PVC/PE/PVDC-aluminium blister, containing 10 tablets.
Cardboard box of 8 PVC/PE/PVDC-aluminium blister, containing 10 tablets.
Cardboard box of 9 PVC/PE/PVDC-aluminium blister, containing 10 tablets.
Cardboard box of 10 PVC/PE/PVDC-aluminium blister, containing 10 tablets.
Cardboard box of 12 PVC/PE/PVDC-aluminium blister, containing 10 tablets.
Cardboard box of 25 PVC/PE/PVDC-aluminium blister, containing 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:
21/02/2024

Manufacturing sites for batch release:
Lelypharma B.V.

Responsible authority:
Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:
240031

Date of authorisation status change:
21/02/2024

Reference member state:
Netherlands

Procedure number:
NL/V/0387/002

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

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Documents

Combined File of all Documents

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