

Tramcoat 80 mg film-coated tablets for dogs

Authorised

- Tramadol hydrochloride

Product identification

Medicine name:

Tramcoat 80 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

80.00 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:

Denmark

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:

15/04/2024

Manufacturing sites for batch release:

Lelypharma B.V.

Responsible authority:

Danish Medicines Agency

Authorisation number:

68862

Date of authorisation status change:

15/04/2024

Reference member state:

Netherlands

Procedure number:

NL/V/0387/004

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)

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

Documents

Combined File of all Documents