

Tramcoat 8 mg film-coated tablets for dogs

Authorised

- Tramadol hydrochloride

Product identification

Medicine name:

Tramcoat 8 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

8.00 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:

Bulgaria

Package description:

Cardboard box of 1 PVC/PE/PVDC-aluminium blister, containing 10 tablets.

Cardboard box of 2 PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

Cardboard box of 3 PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

Cardboard box of 4 PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

Cardboard box of 5 PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

Cardboard box of 6 PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

Cardboard box of 7 PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

Cardboard box of 8 PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

Cardboard box of 9 PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

Cardboard box of 10 PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

Cardboard box of 12 PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

Cardboard box of 25 PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

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:

8/02/2024

Manufacturing sites for batch release:

Lelypharma B.V.

Responsible authority:

Bulgarian Food Safety Authority

Authorisation number:

0022-3238

Date of authorisation status change:

8/02/2024

Reference member state:

Netherlands

Procedure number:

NL/V/0387/001

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

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Labelling

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents