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Tralieve 80 mg chewable tablets for dogs

Authorised

- Tramadol hydrochloride

Product identification

Medicine name:
Tralieve 80 mg chewable 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:
Chewable tablet

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN02AX02

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

Authorisation status:
Valid

Authorised in:
France

Available in:
France

Package description:
Cardboard box of 25 Aluminium - PVC/PE/PVDC blisters of 10 tablets.
Cardboard box of 4 Aluminium - PVC/PE/PVDC blisters of 10 tablets.
Cardboard box of 5 Aluminium - PVC/PE/PVDC blisters of 10 tablets.
Cardboard box of 6 Aluminium - PVC/PE/PVDC blisters of 10 tablets.
Cardboard box of 7 Aluminium - PVC/PE/PVDC blisters of 10 tablets.
Cardboard box of 8 Aluminium - PVC/PE/PVDC blisters of 10 tablets.
Cardboard box of 9 Aluminium - PVC/PE/PVDC blisters of 10 tablets.
Cardboard box of 2 Aluminium - PVC/PE/PVDC blisters of 10 tablets.
Cardboard box of 3 Aluminium - PVC/PE/PVDC blisters of 10 tablets.
Cardboard box containing 10 separate cardboard boxes, each containing 3 Aluminium - PVC/PE/PVDC blisters of 10 tablets.
Cardboard box of 1 Aluminium - PVC/PE/PVDC blister of 10 tablets.
Cardboard box of 10 Aluminium - PVC/PE/PVDC blisters of 10 tablets.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Dechra Regulatory B.V.

Marketing authorisation date:
6/04/2018

Manufacturing sites for batch release:
Lelypharma B.V.
Genera d.d.

Responsible authority:
French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:
FR/V/9293661 2/2018

Date of authorisation status change:
6/04/2018

Reference member state:
Netherlands

Procedure number:
NL/V/0231/002

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)

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 and Labelling

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