Telmitraxx 4 mg/ml oral solution for cats

Authorised

- Telmisartan

Product identification

Medicine name:
Telmitraxx 4 mg/ml oral solution for cats

Active substance:
Telmisartan

Target species:
Cat

Route of administration:
Oral use

Product details

Active substance and strength:
Telmisartan
4.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Oral solution

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QC09CA07

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

Authorisation status:
Valid

Authorised in:
Netherlands

Package description:
HDPE bottle filled with 200 ml. Each bottle is closed with an LDPE plug-in adapter and a tamper-proof polypropylene (PP) closure. Pack size of one bottle and one measuring syringe (3 ml, LDPE barrel and piston, PS plunger).
HDPE bottle filled with 90 ml. Each bottle is closed with an LDPE plug-in adapter and a tamper-proof polypropylene (PP) closure. Pack size of one bottle and one measuring syringe (3 ml, LDPE barrel and piston, PS plunger).
HDPE bottle filled with 60 ml. Each bottle is closed with an LDPE plug-in adapter and a tamper-proof polypropylene (PP) closure. Pack size of one bottle and one measuring syringe (3 ml, LDPE barrel and piston, PS plunger).
HDPE bottle filled with 30 ml. Each bottle is closed with an LDPE plug-in adapter and a tamper-proof polypropylene (PP) closure. Pack size of one bottle and one measuring syringe (3 ml, LDPE barrel and piston, PS plunger).

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 18 of Regulation (EU) 2019/6)

Marketing authorisation holder:
Alfasan Nederland B.V.

Marketing authorisation date:

17/07/2023

Manufacturing sites for batch release:
Lelypharma B.V.
Alfasan Nederland B.V.

Responsible authority:
Medicines Evaluation Board

Authorisation number:
REG NL 129763

Date of authorisation status change:
24/08/2023

Reference member state:
Netherlands

Procedure number:
NL/V/0386/001

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)

Generic of:
600000004056

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

Documents

Combined File of all Documents

English (PDF)
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NLV0386001DC_Telmitraxx_RMS Final PuAR.pdf