Temprace 0.5 mg/ml Solution for Injection for Dogs and Cats

Authorised

- Acepromazine maleate

Product identification

Medicine name:
Temprace 0.5 mg/ml Solution for Injection for Dogs and Cats

Active substance:
Acepromazine maleate

Target species:
Dog
Cat

Route of administration:
Intravenous use

Product details

Active substance and strength:
Acepromazine maleate
0.68 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN05AA04

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

Authorisation status:
Valid

Authorised in:
Ireland

Package description:
Clear type I glass vial of 10 ml closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box
Clear type I glass vial of 20 ml closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box
Clear type I glass vial of 100 ml closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box

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:
Le Vet. Beheer B.V.

Marketing authorisation date:
25/05/2018

Manufacturing sites for batch release:
Produlab Pharma B.V.

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10475/033/001

Date of authorisation status change:
25/05/2018

Reference member state:
Netherlands

Procedure number:
NL/V/0321/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France 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