Tsefalen 50mg/ml Powder for Oral Suspension for Dogs up to 20kg and Cats

Authorised

- Cefalexin

Product identification

Medicine name:
Tsefalen 50mg/ml Powder for Oral Suspension for Dogs up to 20kg and Cats
Tsefalen 50mg/ml poeder voor orale suspensie voor honden tot 20 kg en katten

Active substance:
Cefalexin

Target species:
Cat
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Cefalexin
50.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Powder for oral suspension

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01DB01

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

Authorisation status:
Valid

Authorised in:
Netherlands

Package description:
Carton box with 1 bottle containing 40.0 g of powder providing 60 ml of suspension after reconstitution and 1 syringe of 5 ml
Carton box with 1 bottle containing 66.6 g of powder providing 100 ml of suspension after reconstitution and 1 syringe of 5 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Nextmune Italy S.r.l.

Marketing authorisation date:
18/08/2020

Manufacturing sites for batch release:
Acs Dobfar S.p.A.

Responsible authority:

Medicines Evaluation Board

Authorisation number:
REG NL 124490

Date of authorisation status change:
23/02/2022

Reference member state:
Italy

Procedure number:
IT/V/0142/001

Concerned member states:
Austria Belgium Bulgaria Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Ireland Latvia Liechtenstein Lithuania Luxembourg Malta Netherlands 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

English (PDF)
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