Tsefalen 500 mg film-coated tablets for dogs

Authorised

- Cefalexin

Product identification

Medicine name:
Tsefalen 500 mg film-coated tablets for dogs
Tsefalen 500 mg filmovertrukne tabletter

Active substance:
Cefalexin

Target species:
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Cefalexin
500.00 milligram(s) / 1.00 Tablet

Pharmaceutical form:
Film-coated tablet

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01DB01

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

Authorisation status:
Valid

Authorised in:
Denmark

Package description:
Carton box containing 9 PVC/Aluminium blister pack of 12 tablets, with a total of 108 tablets
Carton box containing 1 PVC/Aluminium blister pack of 12 tablets
Carton box containing 3 PVC/Aluminium blister pack of 12 tablets, with a total of 36 tablets

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:
26/07/2012

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

Responsible authority:
Danish Medicines Agency

Authorisation number:
49263

Date of authorisation status change:
26/07/2012

Reference member state:
Italy

Procedure number:
IT/V/0125/001

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

Summary of Product Characteristics

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