Osteopen 100 mg/ml Solution for injection for dogs

Authorised

- Pentosan polysulfate sodium

Product identification

Medicine name:
Osteopen 100 mg/ml Solution for injection for dogs
Osteopen vet 100 mg/ml injektioneste, liuos

Active substance:
Pentosan polysulfate sodium

Target species:
Dog

Route of administration:
Subcutaneous use

Product details

Active substance and strength:
Pentosan polysulfate sodium
100.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QM01AX90

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

Authorisation status:
Valid

Authorised in:
Finland

Package description:
Colourless glass vial fitted with a grey chlorobutyl stopper and sealed by a lacquered aluminium cap.Package size:1 x 10ml
Colourless glass vial fitted with a grey chlorobutyl stopper and sealed by a lacquered aluminium cap.Package size:1 x 20ml

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:
Chanelle Pharmaceuticals Manufacturing Limited

Marketing authorisation date:
29/12/2019

Manufacturing sites for batch release:
Chanelle Pharmaceuticals Manufacturing Limited
Labiana Life Sciences S.A.

Responsible authority:
Finnish Medicines Agency

Authorisation number:
35154

Date of authorisation status change:
29/12/2019

Reference member state:
Ireland

Procedure number:
IE/V/0382/001

Concerned member states:
Austria Belgium Cyprus Czechia Denmark Finland France Germany Greece Hungary Iceland Italy 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

Summary of Product Characteristics

Combined File of all Documents