Osteopen 100 mg/ml Solution for injection for dogs

Not authorised

- Pentosan polysulfate sodium

Product identification

Medicine name:
Osteopen 100 mg/ml Solution for injection for dogs
Osteopen 100 mg/ml Stungulyf, lausn fyrir hunda

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

Withdrawal period by route of administration:

Subcutaneous use:

- **Dog**

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QM01AX90

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

Authorisation status:
Surrendered

Authorised in:
Iceland

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:
22/03/2021

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

Responsible authority:
Icelandic Medicines Agency

Authorisation number:
IS/2/21/005/01

Date of authorisation status change:
23/10/2023

Reference member state:
Ireland

Procedure number:
IE/V/0382/001

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

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