Defixopzyl 200 mg/ml solution for injection, pig (piglet) and cattle (calf)

Authorised

- IRON(III)-HYDROXIDE DEXTRAN COMPLEX

Product identification

Medicine name:
Defixopzyl
Defixopzyl 200 mg/ml solution for injection, pig (piglet) and cattle (calf)

Active substance:
IRON(III)-HYDROXIDE DEXTRAN COMPLEX

Target species:
Pig (piglet)
Cattle (calf)

Route of administration:
Subcutaneous use
Intramuscular use
Subcutaneous use
Intramuscular use

Product details

Active substance and strength:
IRON(III)-HYDROXIDE DEXTRAN COMPLEX

519.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Subcutaneous use:

- **Pig (piglet)**

  - All relevant tissues. 0 day

- **Cattle (calf)**

Intramuscular use:

- **Pig (piglet)**

  - All relevant tissues. 0 day

- **Cattle (calf)**

Subcutaneous use:

- **Pig (piglet)**

  - All relevant tissues. 0 day

- **Cattle (calf)**

Intramuscular use:

- **Pig (piglet)**

  - All relevant tissues. 0 day

- **Cattle (calf)**

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QB03AC

Legal status of supply:

Veterinary medicinal product not subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Ireland

Package description:

Carton box with 1 vial (glass) with 100 ml

Carton box with 10 vials (glass) with 100 ml

Carton box with 12 vials (glass) with 100 ml
Carton box with 20 vials (glass) with 100 ml
Carton box with 48 vials (glass) with 100 ml
Carton box with 5 vials (glass) with 100 ml
Carton box with 5 vials (LDPE) with 100 ml
Carton box with 1 vial (LDPE) with 100 ml
Carton box with 1 vial (LDPE) with 200 ml
Carton box with 10 vials (LDPE) with 100 ml
Carton box with 12 vials (LDPE) with 100 ml
Carton box with 12 vials (LDPE) with 200 ml
Carton box with 20 vials (LDPE) with 100 ml
Carton box with 48 vials (LDPE) with 100 ml
Carton box with 5 vials (LDPE) with 200 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Complete application (stand-alone) - Directive No 2001/82/EC

Marketing authorisation holder:
Pharmacosmos A/S

Marketing authorisation date:
25/08/2023

Manufacturing sites for batch release:
Pharmacosmos A/S

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10794/002/001

Date of authorisation status change:

25/08/2023

Reference member state:
Sweden

Procedure number:
SE/V/0124/001

Concerned member states:
Belgium Denmark France Germany Ireland Italy Netherlands Poland Spain

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

Documents

Summary of Product Characteristics

Package Leaflet

Labelling

eu-puar-sev0124001-mr-defixopzyl-solution-for-injection-en.pdf

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