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Fixplan 200 IU/ml Lyophilisate and Solvent for Solution for Injection

Authorised

- Gonadotropin, equine, serum

Product identification

Medicine name:
Fixplan 200 IU/ml Lyophilisate and Solvent for Solution for Injection

Active substance:
Gonadotropin, equine, serum

Target species:
Cattle
Sheep
Pig

Route of administration:
Intramuscular use
Subcutaneous use

Product details

Active substance and strength:
Gonadotropin, equine, serum

200.00 international unit(s) / 1.00 millilitre(s)

Pharmaceutical form:
Lyophilisate and solvent for solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Sheep**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Pig**
  - Meat and offal. 0 day

Subcutaneous use:

- **Pig**
  - Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QG03GA03

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

Authorisation status:
Valid

Authorised in:
United Kingdom (Northern Ireland)

Available in:
United Kingdom (Northern Ireland)

Package description:
Lyophilisate: 8 ml colourless type I glass vial closed with a grey bromobutyl rubber stopper, aluminium seals and prolypropylene caps. Solvent: 30 ml colourless type II glass vial closed with a grey bromobutyl rubber stopper, aluminium seals and polypropylene caps. Carton box containing 1 vial of 5,000 IU lyophilisate and 1 vial of solvent (25 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:
Syn Vet-Pharma Ireland Limited

Marketing authorisation date:
3/03/2021

Manufacturing sites for batch release:
Laboratorios Ovejero S.A.U.

Responsible authority:
The Veterinary Medicines Directorate

Authorisation number:
Vm 54400/4001

Date of authorisation status change:
22/12/2021

Reference member state:
Ireland

Procedure number:
IE/V/0448/001

Concerned member states:
Belgium France Germany Hungary Italy Netherlands Poland Portugal Spain 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