

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 polypropylene 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