HIPRABOVIS-BALANCE

Authorised

- Bovine parainfluenza virus 3, strain SF-4, Inactivated
- Bovine viral diarrhoea virus, strain NADL, Inactivated
- Bovine respiratory syncytial virus, strain Lym-56, Live

Product identification

Medicine name:
HIPRABOVIS-BALANCE
Hiprabovis Balance

Active substance:
Bovine parainfluenza virus 3, strain SF-4, Inactivated
Bovine viral diarrhoea virus, strain NADL, Inactivated
Bovine respiratory syncytial virus, strain Lym-56, Live

Target species:
Cattle (calf)
Cattle (cow)
Cattle (heifer)

Route of administration:
Intramuscular use
Subcutaneous use

Product details

Active substance and strength:
Bovine parainfluenza virus 3, strain SF-4, Inactivated

16.00 haemagglutination inhibiting unit(s) / 1.00 Dose

Bovine viral diarrhoea virus, strain NADL, Inactivated
20.00 serum neutralising unit(s) / 1.00 Dose

Bovine respiratory syncytial virus, strain Lym-56, Live
10000.00 tissue culture infective dose 50 / 1.00 Dose

Pharmaceutical form:

Lyophilisate and suspension for suspension for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle (calf)**
  - Meat and offal. 0 day
- **Cattle (cow)**
  - Meat and offal. 0 day
- **Cattle (heifer)**
  - Meat and offal. 0 day

Subcutaneous use:

- **Cattle (calf)**
  - Meat and offal. 0 day
- **Cattle (cow)**
  - Meat and offal. 0 day
- **Cattle (heifer)**
  - Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AH

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Valid

Authorised in:

Portugal

Package description:
Box with 1 vial lyophilised fraction (80 doses) + 1 vial of 250 ml of liquid fraction (containing 240 ml)
Box with 1 vial lyophilised fraction (30 doses) + 1 vial of 100 ml of liquid fraction (containing 90 ml)
Box with 1 vial of lyophilised fraction (5 doses) + 1 vial of 20 ml of liquid fraction (containing 15 ml)
Box with 1 vial lyophilised fraction (25 doses) + 1 vial of 100 ml of liquid fraction

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Informed consent application (Article 13c of Directive No 2001/82/EC)

Marketing authorisation holder:
Laboratorios Hipra S.A.

Marketing authorisation date:
25/10/2010

Manufacturing sites for batch release:
Laboratorios Hipra S.A.

Responsible authority:
Directorate General For Food And Veterinary

Authorisation number:
837/10RIVPT

Date of authorisation status change:
10/10/2022

Reference member state:
Spain

Procedure number:
ES/V/0166/001

Concerned member states:
Portugal

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

Documents

Combined File of all Documents

This document does not exist in this language (English). You can find it in another language below.

Summary of Product Characteristics

Package Leaflet

Labelling

eu-PUAR-hiprabovis-balance-en.pdf
