GALLIMUNE 302 ND+IB+EDS Water-in oil emulsion for injection

Authorised

- Eggdrop syndrome-1976 virus, strain V127, Inactivated
- Infectious bronchitis virus, type Massachusetts, strain M41, Inactivated
- Newcastle disease virus, strain Ulster 2C, Inactivated

Product identification

Medicine name:
GALLIMUNE 302 ND+IB+EDS Water-in oil emulsion for injection

Active substance:
Eggdrop syndrome-1976 virus, strain V127, Inactivated

Infectious bronchitis virus, type Massachusetts, strain M41, Inactivated

Newcastle disease virus, strain Ulster 2C, Inactivated

Target species:
Chicken (for reproduction)

Route of administration:
Intramuscular use

Product details

Active substance and strength:

Eggdrop syndrome-1976 virus, strain V127, Inactivated
162.00 log10 haemagglutination inhibiting unit(s) / 0.30 millilitre(s)

Infectious bronchitis virus, type Massachusetts, strain M41, Inactivated
10.00 log10 haemagglutination inhibiting unit(s) / 0.30 millilitre(s)

Newcastle disease virus, strain Ulster 2C, Inactivated
10.00 log10 haemagglutination inhibiting unit(s) / 0.30 millilitre(s)

Pharmaceutical form:
Emulsion for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Chicken (for reproduction)**
  - Egg. 0 day
  - Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI01AA13

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

Authorisation status:
Valid

Authorised in:
Slovenia

Package description:
(ID4): 1 Box with 10 Bottle (PolyPropylene) with 300 millilitre(s) (3000 millilitre(s))
(ID3): 1 Box with 1 Bottle (PolyPropylene) with 300 millilitre(s) (300 millilitre(s))
(ID1): 1 Box with 1 Bottle (PolyPropylene) with 150 millilitre(s) (150 millilitre(s))
(ID2): 1 Box with 10 Bottle (PolyPropylene) with 150 millilitre(s) (1500 millilitre(s))

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Immunological veterinary medicinal product application (Article 13d of Directive No 2001/82/EC)

Marketing authorisation holder:
Boehringer Ingelheim Animal Health France

Marketing authorisation date:
7/04/2006

Manufacturing sites for batch release:
Boehringer Ingelheim Animal Health France

Responsible authority:
Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia

Authorisation number:
MR/V/0148/001

Date of authorisation status change:
7/04/2006

Reference member state:
Germany

Procedure number:
DE/V/0227/001

Concerned member states:
Belgium Cyprus Czechia Denmark Finland France Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Netherlands Poland Portugal Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

Summary of Product Characteristics

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

Package Leaflet and Labelling

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