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

Not authorised

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

Product identification

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

Active substance:
Newcastle disease virus, strain Ulster 2C, Inactivated

Infectious bronchitis virus, type Massachusetts, strain M41, Inactivated

Eggdrop syndrome-1976 virus, strain V127, Inactivated

Target species:
Chicken (for reproduction)

Route of administration:
Intramuscular use

Product details

Active substance and strength:

Newcastle disease virus, strain Ulster 2C, Inactivated
10.00 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)

Eggdrop syndrome-1976 virus, strain V127, Inactivated
162.00 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

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Authorisation status:

Surrendered

Authorised in:

Sweden

Package description:

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

(ID4): 1 Box with 10 Bottle (PolyPropylene) with 300 millilitre(s) (3000 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 Denmark A/S

Marketing authorisation date:
21/01/2005

Manufacturing sites for batch release:
Boehringer Ingelheim Animal Health France

Responsible authority:
Swedish Medical Products Agency

Authorisation number:
21041

Date of authorisation status change:
16/01/2024

Reference member state:
Germany

Procedure number:
DE/V/0227/001

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

Documents

Summary of Product Characteristics

English (PDF)
Published on: 28/01/2022
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Combined File of all Documents