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Primun Newcastle C30 Lyophilisate for suspension

Authorised

- Newcastle disease virus, strain NDV_CLS, Live

Product identification

Medicine name:
Primun Newcastle C30 Lyophilisate for suspension

Active substance:
Newcastle disease virus, strain NDV_CLS, Live

Target species:
Chicken

Route of administration:
Oculonasal use
Nebulisation use
In drinking water use

Product details

Active substance and strength:
Newcastle disease virus, strain NDV_CLS, Live
6.00 log 10 50% embryo infective dose / 1.00 Dose

Pharmaceutical form:

Lyophilisate for oculonasal suspension/use in drinking water

Withdrawal period by route of administration:

Oculonasal use:

- **Chicken**
  - Meat and offal. 0 day
  - Egg. 0 day

Nebulisation use:

- **Chicken**
  - Egg. 0 day
  - Meat and offal. 0 day

In drinking water use:

- **Chicken**
  - Egg. 0 day
  - Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI01AD06

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

Authorisation status:
Valid

Authorised in:
Germany

Package description:
(ID1) 1000 Dose: Box (Cardboard) with 1 Bottle (Glass type I) with 1000 Dose, closed with Stopper (Bromobutyl Rubber) and Cap (Aluminium) and Cap (Information nicht vorhanden)

(ID2) 10000 Dose: Box (Cardboard) with 10 Bottle (Glass type I) each with 1000 Dose, closed with Stopper (Bromobutyl Rubber) and Cap (Aluminium) and Cap (Information nicht vorhanden)
(ID5) 5000 Dose: Box (Cardboard) with 1 Bottle (Glass type I) with 5000 Dose, closed with Stopper (Bromobutyl Rubber) and Cap (Aluminium) and Cap (Information nicht vorhanden)
(ID6) 50000 Dose: Box (Cardboard) with 10 Bottle (Glass type I) each with 5000 Dose, closed with Stopper (Bromobutyl Rubber) and Cap (Aluminium) and Cap (Information nicht vorhanden)

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:
Laboratorios Calier S.A.

Marketing authorisation date:
29/05/2018

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

Responsible authority:
Paul-Ehrlich-Institut

Authorisation number:
PEI.V.11935.01.1

Date of authorisation status change:
29/05/2018

Reference member state:

Germany

Procedure number:
DE/V/0273/001

Concerned member states:
Italy Poland Portugal Spain

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Documents

Combined File of all Documents

English (PDF)
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