# 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 Stopfen (bromobutyl rubber) and Kappe (aluminium) and Deckel (No information)

(ID2) 10000 Dose: Box (cardboard) with 10 Bottle (Glass type I) each with 1000 Dose, closed with Stopfen (bromobutyl rubber) and Kappe (aluminium) and Deckel (No information)
(ID5) 5000 Dose: Box (cardboard) with 1 Bottle (Glass type I) with 5000 Dose, closed with Stopfen (bromobutyl rubber) and Kappe (aluminium) and Deckel (No information)
(ID6) 50000 Dose: Box (cardboard) with 10 Bottle (Glass type I) each with 5000 Dose, closed with Stopfen (bromobutyl rubber) and Kappe (aluminium) and Deckel (No information)

## 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.

**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

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

## Documents

Combined File of all Documents

English (PDF)
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