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Poulvac Bursa Plus Lyophilisate for suspension in drinking water

Authorised

- Infectious bursal disease virus, strain V877 (intermediate plus), Live

Product identification

Medicine name:
Poulvac Bursa Plus Lyophilisate for suspension in drinking water

Active substance:
Infectious bursal disease virus, strain V877 (intermediate plus), Live

Target species:
Chicken

Route of administration:
In drinking water use

Product details

Active substance and strength:
Infectious bursal disease virus, strain V877 (intermediate plus), Live
158.00 50% Embryo Infective Dose / 1.00 Dose

Pharmaceutical form:
Lyophilisate for oculonasal suspension/use in drinking water

Withdrawal period by route of administration:

In drinking water use:

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

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI01AD09

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Valid

Authorised in:

Germany

Available in:

Germany

Package description:

(ID1) 1000 Dose: Box (cardboard) with 1 Bottle (Glass type I) with 1000 Dose, closed with Stopper (butyl rubber) and Kappe (aluminium)
(ID2) 2000 Dose: Box (cardboard) with 1 Bottle (Glass type I) with 2000 Dose, closed with Stopper (butyl rubber) and Kappe (aluminium)
(ID3) 5000 Dose: Box (cardboard) with 1 Bottle (Glass type I) with 5000 Dose, closed with Stopper (butyl rubber) and Kappe (aluminium)
(ID4) 10000 Dose: Box (cardboard) with 10 Bottle (Glass type I) each with 1000 Dose, closed with Stopper (butyl rubber) and Kappe (aluminium)
(ID5) 20000 Dose: Box (cardboard) with 10 Bottle (Glass type I) each with 2000 Dose, closed with Stopper (butyl rubber) and Kappe (aluminium)
(ID6) 50000 Dose: Box (cardboard) with 10 Bottle (Glass type I) each with 5000 Dose, closed with Stopper (butyl rubber) and Kappe (aluminium)

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:
Zoetis Deutschland GmbH

Marketing authorisation date:
29/07/2010

Manufacturing sites for batch release:
Zoetis Manufacturing & Research Spain S.L.

Responsible authority:
Paul-Ehrlich-Institut

Authorisation number:
PEI.V.04760.01.1

Date of authorisation status change:
22/04/2013

Reference member state:
Germany

Procedure number:
DE/V/0278/001

Concerned member states:
Belgium Greece Ireland Italy Lithuania Netherlands Poland Portugal Romania Slovenia 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

English (PDF)
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