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CEVAC MASS L lyophilisate for oculonasal suspension for chickens

Authorised

- Infectious bronchitis virus, type Massachusetts, strain B-48, Live

Product identification

Medicine name:
CEVAC MASS L lyophilisate for oculonasal suspension for chickens

Active substance:
Infectious bronchitis virus, type Massachusetts, strain B-48, Live

Target species:
Chicken (broiler)

Route of administration:
Nebulisation use

Product details

Active substance and strength:
Infectious bronchitis virus, type Massachusetts, strain B-48, Live
4.30 log 10 50% embryo infective dose / 1.00 Dose

Pharmaceutical form:
Lyophilisate for oculonasal suspension

Withdrawal period by route of administration:
Nebulisation use:

- **Chicken (broiler)**
  - Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI01AD07

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

Authorisation status:
Valid

Authorised in:
Denmark

Available in:
Denmark

Package description:
The vaccine is supplied in 3 or 10 ml type I glass vials, sealed with bromobutyl rubber stoppers and aluminium caps with plastic (flip-off) tops. 1x1000 dose.
The vaccine is supplied in 3 or 10 ml type I glass vials, sealed with bromobutyl rubber stoppers and aluminium caps with plastic (flip-off) tops. 1x2500 dose.
The vaccine is supplied in 3 or 10 ml type I glass vials, sealed with bromobutyl rubber stoppers and aluminium caps with plastic (flip-off) tops. 1x5000 dose.
The vaccine is supplied in 3 or 10 ml type I glass vials, sealed with bromobutyl rubber stoppers and aluminium caps with plastic (flip-off) tops. 10x1000 dose.
The vaccine is supplied in 3 or 10 ml type I glass vials, sealed with bromobutyl rubber stoppers and aluminium caps with plastic (flip-off) tops. 10x2500 dose.
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The vaccine is supplied in 3 or 10 ml type I glass vials, sealed with bromobutyl rubber stoppers and aluminium caps with plastic (flip-off) tops. 20x1000 dose.
The vaccine is supplied in 3 or 10 ml type I glass vials, sealed with bromobutyl rubber stoppers and aluminium caps with plastic (flip-off) tops. 20x2500 dose.
The vaccine is supplied in 3 or 10 ml type I glass vials, sealed with bromobutyl rubber stoppers and aluminium caps with plastic (flip-off) tops. 20x5000 dose.

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:
Ceva-Phylaxia Zrt.

Marketing authorisation date:
28/06/2016

Manufacturing sites for batch release:
Ceva-Phylaxia Zrt.

Responsible authority:
Danish Medicines Agency

Authorisation number:
56876

Date of authorisation status change:
28/06/2016

Reference member state:
Hungary

Procedure number:
HU/V/0125/001

Concerned member states:

Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Ireland Italy Latvia Lithuania Netherlands Poland Portugal Romania Slovakia Slovenia Spain Sweden

United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

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Combined File of all Documents