Nextmune concentrate and solvent for suspension for injection for chickens

Authorised

- Infectious bursal disease virus, strain Winterfield 2512 (intermediate plus), Live

Product identification

Medicine name:
Nextmune concentrate and solvent for suspension for injection for chickens
Nextmune koncentrat og solvens til injektionsvæske, suspension

Active substance:
Infectious bursal disease virus, strain Winterfield 2512 (intermediate plus), Live

Target species:
Chicken (broiler)
Chicken (embryonated eggs)

Route of administration:
Subcutaneous use
In ovo

Product details

Active substance and strength:

Infectious bursal disease virus, strain Winterfield 2512 (intermediate plus), Live
2.70 log 10 50% embryo infective dose / 1.00 Dose

Pharmaceutical form:
Concentrate and solvent for suspension for injection

Withdrawal period by route of administration:
Subcutaneous use:

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

In ovo:

- **Chicken (embryonated eggs)**
  - Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI01AD09

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

Authorisation status:
Valid

Authorised in:
Denmark

Package description:
bag containing 1600 ml of solvent
bag containing 1200 ml of solvent
bag containing 800 ml of solvent
bag containing 400 ml of solvent
One ampoule of 5 ml containing 8000 doses
One ampoule of 5 ml containing 4000 doses
One ampoule of 5 ml containing 2000 doses
One ampoule of 2 ml containing 4000 doses

One ampoule of 2 ml containing 2000 doses
bag containing 1000 ml of solvent

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application - Known active substance (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Ceva-Phylaxia Zrt.

Marketing authorisation date:
5/08/2020

Manufacturing sites for batch release:
Ceva-Phylaxia Zrt.

Responsible authority:
Danish Medicines Agency

Authorisation number:
61869

Date of authorisation status change:
5/08/2020

Reference member state:
Spain

Procedure number:
ES/V/0337/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia France Germany Greece Hungary Ireland Italy Latvia Lithuania Netherlands Poland Portugal Romania Slovakia Slovenia United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

English (PDF)
Published on: 22/12/2023
Download

Package Leaflet

Labelling

Combined File of all Documents