# Nextmune concentrate and solvent for suspension for injection for chickens

Authorised

- Infectious bursal disease virus, strain Winterfield 2512, Live

## Product identification

**Medicine name:**
Nextmune concentrate and solvent for suspension for injection for chickens
Nextmune Konzentrat und Lösungsmittel zur Herstellung einer Injektionssuspension für Hühner

**Active substance:**
Infectious bursal disease virus, strain Winterfield 2512, Live

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

**Route of administration:**
In ovo
Subcutaneous use

## Product details

**Active substance and strength:**
Infectious bursal disease virus, strain Winterfield 2512, 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:**

**In ovo:**

- **Chicken (embryonated eggs)**

**Subcutaneous use:**

- **Chicken (broiler)**

**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QI01AD09

**Legal status of supply:**

Medicinal product on medical prescription for non-renewable delivery

**Authorisation status:**

Valid

**Authorised in:**

Austria

**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:**
26/04/2021

**Manufacturing sites for batch release:**
Ceva-Phylaxia Veterinary Biologicals Co. Ltd.

**Responsible authority:**
Austrian Agency For Health And Food Safety

**Authorisation number:**
840627

**Date of authorisation status change:**
26/04/2021

**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

Package Leaflet

English (PDF)
Published on: 22/12/2023
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Summary of Product Characteristics

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

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