

# 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  
NEXMUNE, concentrat și solvent pentru suspensie injectabilă pentru pui de găină

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### Active substance:

Infectious bursal disease virus, strain Winterfield 2512, Live

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### Target species:

Chicken (embryonated eggs)  
Chicken (broiler)

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### Route of administration:

In ovo  
Subcutaneous use

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## 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

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**Pharmaceutical form:**

Concentrate and solvent for suspension for injection

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**Withdrawal period by route of administration:****In ovo:**

- Chicken (embryonated eggs)

**Subcutaneous use:**

- Chicken (broiler)
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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QI01AD09

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Romania

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**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

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Full application - Known active substance (Article 12(3) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Ceva Sante Animale Romania S.R.L.

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**Marketing authorisation date:**

14/06/2020

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**Manufacturing sites for batch release:**

Ceva-Phylaxia Veterinary Biologicals Co. Ltd.

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**Responsible authority:**

Institute For Control Of Biological Products And Veterinary Medicines

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**Authorisation number:**

200070

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**Date of authorisation status change:**

7/06/2021

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**Reference member state:**

Spain

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**Procedure number:**

ES/V/0337/001

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**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)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

### Summary of Product Characteristics

English (PDF)

Published on: 22/12/2023

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### Package Leaflet

### Labelling

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