

# 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 koncentrāts un šķīdinātājs suspensijas injekcijām pagatavošanai vistām

### 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

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**Withdrawal period by route of administration:****Subcutaneous use:**

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**Chicken (broiler)**

- Meat and offal. 0 day

**In ovo:**

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**Chicken (embryonated eggs)**

- Meat and offal. 0 day

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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:**

Latvia

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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-Phylaxia Zrt.

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**Marketing authorisation date:**

21/09/2020

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**Manufacturing sites for batch release:**

Ceva-Phylaxia Zrt.

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**Responsible authority:**

Food And Veterinary Service

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**Authorisation number:**

V/DCP/20/0046

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**Date of authorisation status change:**

21/09/2020

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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

Labelling

Combined File of all Documents

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