

# CEVAC TRANSMUNE lyophilisate for suspension for injection with solvent for chickens

Authorised

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

## Product identification

**Medicine name:**

CEVAC TRANSMUNE lyophilisate for suspension for injection with solvent for chickens

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**Active substance:**

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

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**Target species:**

Chicken (embryonated eggs)  
Chicken

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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 (intermediate plus),  
Inactivated  
0.10 50% Protective Dose / 1.00 Dose

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**Pharmaceutical form:**

Lyophilisate for suspension for injection

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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:**

Germany

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**Package description:**

Cardboard box with single glass vial (Type I) of 10 ml containing 2000 doses, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

Cardboard box with single glass vial (Type I) of 10 ml containing 2500 doses, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

Cardboard box with single glass vial (Type I) of 10 ml containing 4000 doses, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

Cardboard box with single glass vial (Type I) of 10 ml containing 5000 doses, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

Cardboard box with single glass vial (Type I) of 13.5 ml containing 8000 doses, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

Cardboard box with 20 glass vials (Type I) of 10 ml containing 2000 doses, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

Cardboard box with 20 glass vials (Type I) of 10 ml containing 2500 doses, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

Cardboard box with 20 glass vials (Type I) of 10 ml containing 4000 doses, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

Cardboard box with 20 glass vials (Type I) of 10 ml containing 5000 doses, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

Cardboard box with 20 glass vials (Type I) of 13.5 ml containing 8000 doses, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Immunological veterinary medicinal product application (Article 13d of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Ceva Tiergesundheit GmbH

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**Marketing authorisation date:**

15/10/2010

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**Manufacturing sites for batch release:**

Ceva-Phylaxia Zrt.

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**Responsible authority:**

Paul-Ehrlich-Institut

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**Authorisation number:**

PEI.V.11421.01.1

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**Date of authorisation status change:**

8/02/2013

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**Reference member state:**

Hungary

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**Procedure number:**

HU/V/0141/002

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**Concerned member states:**

Bulgaria Cyprus Czechia Estonia France Germany Greece Ireland Italy  
Latvia Lithuania Netherlands Poland Portugal Romania Slovakia Slovenia  
Spain 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

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Combined File of all Documents