SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ultifend ND IBD concentrate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.05 ml or 0.2 ml) contains:

Active substance:
Cell-associated live recombinant turkey herpesvirus (rHVT/ND/IBD), expressing the fusion protein of Newcastle disease virus and the VP2 protein of infectious bursal disease virus:
min. 4,000, max. 12,000 PFU*

*Plaque forming units

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate and solvent for suspension for injection
Concentrate: yellowish brown homogeneous concentrate
Solvent: clear, orange to red solution

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and chicken embryonated eggs.

4.2 Indications for use, specifying the target species

For the active immunisation of one-day-old chicks or 18-day-old chicken embryonated eggs:

- to reduce mortality, clinical signs and lesions caused by Newcastle disease virus (NDV) and to reduce virus shedding
- to reduce mortality, clinical signs and bursa lesions caused by very virulent infectious bursal disease virus (IBDV)
- to reduce mortality, clinical signs and lesions caused by classical Marek's disease virus (MDV).

Onset of immunity:

Broiler chickens	NDV: 4 weeks
	IBDV: 3 weeks
	MDV: 9 days

Layer chickens	NDV: 4 weeks
	IBDV: 4 weeks
	MDV: 9 days

Duration of immunity:

Broiler chickens	NDV: 9 weeks
	IBDV: 9 weeks
	MDV: life long
Layer chicken	NDV: 18 weeks
	IBDV: 9 weeks
	MDV: life long

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

The onset of immunity for IBD in chickens with very high levels of maternally derived antibodies against IBDV or MDV may be delayed by about one week, when vaccinated with this veterinary medicinal product.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate all the chickens in a flock at the same time.

Vaccinated chickens may excrete the vaccine strain up to 49 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided.

The vaccine strain can spread to turkeys. Safety trials have shown that the excreted vaccine strain is not harmful in turkeys. However, appropriate veterinary and husbandry measures such as cleaning and disinfection procedures should be taken to avoid spread of the vaccine strain to turkeys.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Liquid nitrogen containers and vaccine should be handled by properly trained personnel only.

Personal protective equipment consisting of protective gloves, goggles and boots should be worn when handling the veterinary medicinal product, before withdrawing from liquid nitrogen, during the ampoule thawing and opening operations.

Frozen glass ampoules can explode during sudden temperature changes. Store and use liquid nitrogen only in a dry and well-ventilated place. Inhalation of the vapour of liquid nitrogen is dangerous.

Personnel involved in the treatment of vaccinated birds should use hygiene principles and take particular care in handling litter from vaccinated chickens.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

In ovo and subcutaneous use.

In ovo administration: one dose of 0.05 ml to be administered to 18-day-old chicken embryonated eggs.

Subcutaneous administration: one dose of 0.2 ml to be administered to one-day-old chicken, in the skin of the neck.

Preparation of vaccine:

Use sterile devices and equipment for reconstitution and for administration of the vaccine. Before withdrawing vaccine from liquid nitrogen container, protect hands with gloves and use goggles and boots. When removing an ampoule from the strip, hold palm of gloved hand away from body and face.

1. After matching the dose size of the vaccine with the solvent size, quickly remove from liquid nitrogen container the exact number of ampoules needed.
2. Draw up 2 to 5 ml of solvent into a 5 to 10 ml sterile syringe. Use at least 18-gauge needles.
3. Thaw rapidly the contents of the ampoules by gentle agitation in water at 27-39 °C.
4. As soon as they are completely thawed, open ampoules holding them at arm's length in order to prevent any risk of injury should the ampoule break.
5. Once the ampoule is open, slowly draw up the content into the needle already containing 2 to 5 ml solvent.

6. Transfer the suspension into the solvent bag. The diluted vaccine prepared as described is mixed by gentle agitation.
7. Withdraw a portion of the diluted vaccine into the syringe to rinse ampoule. Remove the washing from the ampoule and inject it gently into the solvent bag. Repeat it one or two times.
8. The diluted vaccine prepared as described is mixed by gentle agitation so as to be ready for use.

Repeat the operations in point 2 to7 for the appropriate number of ampoules to be thawed.

The ready to use vaccine is a red, slightly opalescent liquid.

Proposed dilutions for *in-ovo* administration:

One single dose of 0.05 ml is injected into each 18-day-old chicken embryonated egg.

Number of vaccine vials	Solvent	Volume of one dose
4 x 2000 doses	400 ml	0.05 ml
2 x 4000 doses	400 ml	0.05 ml
4 x 4000 doses	800 ml	0.05 ml
5 x 4000 doses	1000 ml	0.05 ml
6 x 4000 doses	1200 ml	0.05 ml
8 x 4000 doses	1600 ml	0.05 ml

Proposed dilutions for subcutaneous administration:

One single injection of 0.2 ml per chick is applied at one day of age.

Number of vaccine vials	Solvent	Volume of one dose
2 x 1000 doses	400 ml	0.2 ml
1 x 2000 doses	400 ml	0.2 ml
1 x 4000 doses	800 ml	0.2 ml
3 x 2000 doses	1200 ml	0.2 ml
2 x 4000 doses	1600 ml	0.2 ml

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No symptoms were observed after the administration of a 10-fold dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Aves, live viral vaccines for domestic fowl.
ATCvet code: QI01AD16

The vaccine contains a cell-associated, live recombinant herpesvirus of turkey (HVT, Marek's disease virus serotype 3) which is genetically modified to express the fusion (F) gene of Newcastle disease virus (NDV) and the virion protein (VP2) gene of infectious bursal disease virus (IBDV). The vaccine induces active immunity against Newcastle disease, infectious bursal disease (Gumboro disease) and Marek's disease.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Concentrate:
EMEM
L Glutamine
Sodium bicarbonate
Hepes
Bovine serum
Water for injections
Dimethyl sulfoxide

Solvent:
Sucrose
Casein hydrolysate
Sorbitol
Dipotassium hydrogen phosphate
Potassium dihydrogen phosphate
Phenol red
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except the solvent (Cevac Solvent Poultry) supplied for use with the veterinary medicinal product.

6.3 Shelf life

Shelf life of the vaccine as packaged for sale: 18 months
Shelf life of the solvent as packaged for sale: 30 months
Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

Concentrate:
Store and transport frozen in liquid nitrogen (-196 °C).

The liquid nitrogen containers must be checked regularly for liquid nitrogen level and must be refilled as needed.

Solvent:
Store below 25 °C.
Do not freeze.

6.5 Nature and composition of immediate packaging

Concentrate:
2 ml hydrolytic Type I glass ampoules, containing 1000, 2000 or 4000 doses.
The ampoules are put on canes with tag and stored in a liquid nitrogen container.

Solvent:
Plastic bags made of polyvinylchloride: 400 ml, 800 ml, 1000 ml, 1200 ml, 1600 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
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8. MARKETING AUTHORISATION NUMBER

Vm 15052/5001

9. DATE OF FIRST AUTHORISATION

11 June 2021

10. DATE OF REVISION OF THE TEXT

October 2022

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