ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Ampoules of 1,000, 2,000 or 4,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ultifend ND IBD

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

rHVT/ND/IBD

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1,000 doses
2,000 doses
4,000 doses

(in the tag)

4. ROUTE(S) OF ADMINISTRATION

SC or *in ovo* use.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot {number}

(and in the tag)

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe

Buckinghamshire
HP10 0HH
United Kingdom

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Solvent bags of 400 ml, 800 ml, 1000 ml, 1200 ml, 1600 ml

1. NAME OF THE DILUENT

Cevac Solvent Poultry

2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

400 ml
800 ml
1000 ml
1200 ml
1600 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store below 25 °C.
Do not freeze.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Company logo

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT(S)

Each dose (0.05 ml or 0.2 ml) contains:

Active substances:
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 unit

Concentrate: yellowish brown, homogeneous concentrate
Solvent: clear, orange to red solution

4. INDICATION(S)

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

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens and chicken embryonated eggs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

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

9. ADVICE ON CORRECT ADMINISTRATION

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 to 7 for the appropriate number of ampoules to be thawed.

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

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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 (Cevac Solvent Poultry):
Store below 25 °C.
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after {EXP}.

Shelf life after reconstitution according to directions: 2 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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.
Vaccinate healthy animals only.

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.

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

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.

Overdose (symptoms, emergency procedures, antidotes):
No symptoms were observed after the administration of a 10-fold dose of vaccine.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

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.

Package size:

Concentrate: glass ampoules, containing 1000, 2000 or 4000 doses.

Cevac Solvent Poultry: 400 ml, 800 ml, 1000 ml, 1200 ml, 1600 ml in plastic bag.

Not all pack sizes may be marketed.

Approved 14 October 2022