1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis CAV P4 lyophilisate and solvent for suspension for injection for chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.2 ml dose of reconstituted vaccine contains:

Active substance:
Live attenuated CAA virus strain 26P4 ≥ 3.0 $\log_{10}TCID_{50}$

Solvent (Dilavia):
Adjuvant:
dl-α-tocopheryl acetate: 75 mg/ml

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Pancreatic digest of casein
Dextran 70
Sorbitol
Sucrose
Gelatin
Dibasic potassium phosphate
Monobasic potassium phosphate
Solvent Dilavia:
Polysorbate 80
Monobasic potassium phosphate
Disodium phosphate dihydrate
Sodium chloride
Simethicone
Water for injections

Lyophilisate: off-white or cream-coloured pellet.
Dilavia solvent: homogenous white to nearly white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broiler breeders).

3.2 Indications for use for each target species

For active immunisation of broiler breeders to stimulate the production of antibodies to chicken anaemia virus – to reduce mortality and clinical signs due to chicken anaemia virus in progeny produced during the laying period after vaccination.

Onset of immunity: 6 weeks.

Duration of immunity: Antibody at a level which has been shown to prevent excretion of challenge virus has been demonstrated for at least 10 weeks after vaccination under controlled laboratory conditions. There is some limited evidence from use in the field that the duration of immunity may be longer, possibly up to 42 weeks.

3.3 Contraindications

Do not vaccinate birds below 6 weeks of age under any circumstances.
Do not vaccinate birds in the last six weeks before lay or birds in lay. Do not use in multi-age sites.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not use in unhealthy birds. Sick or weak birds will not develop adequate immunity following vaccination.

The vaccine strain can spread to susceptible birds. Special precautions should be taken to avoid spreading of the vaccine strain to very young birds and birds in lay.

A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration. Immuno-competence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands and equipment after vaccinating.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
The vaccine must not be used in the last 6 weeks before lay or during lay.

3.8 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.

3.9 Administration routes and dosage

Reconstitute the vaccine using the solvent provided, allowing 0.2 ml solvent per dose i.e. 200 ml per 1000 doses.

Intramuscular or subcutaneous use.

Administer one dose (0.2 ml) to every bird.

Equipment used for vaccination should be sterile and contain no traces of detergents or disinfectants.

Vaccination programme
The optimum age and route (intramuscular or subcutaneous use) of vaccination depend on the local situation and should be determined by the site veterinarian. The chicks must be at least 6 weeks of age before vaccination and must be vaccinated at least 6 weeks before the expected onset of lay.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No clinical signs have been associated with an overdose of the vaccine.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD04

Live attenuated vaccine which stimulates active immunity against CAV in order to provide passive immunity to the progeny.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:

Vaccine:
In freeze-dried form: 24 months (following up to 12 months storage by the manufacturer at -20ºC).

Solvent:
In glass bottles: 4 years.
In PET bottles: 21 months.

Shelf life after dilution or reconstitution according to the directions:
2 hours.

5.3 Special precautions for storage

Vaccine: Store in a refrigerator (2 °C – 8 °C). Do not freeze. Protect from light.
Solvent: Do not store above +25 °C. Do not freeze. Protect from light.

5.4 Nature and composition of immediate packaging

Vaccine:
Vial of hydrolytical type I glass (Ph. Eur.) containing the freeze-dried pellet containing 500 or 1000 doses. The vial is closed with a halogenobutyl rubber bung (Ph. Eur.) and sealed with a coded aluminium cap.

Solvent (Dilavia):
Vial of hydrolytical type II glass (Ph. Eur.) or PET containing 100 or 200 ml solvent, closed with a halogenobutyl rubber bung (Ph. Eur.) and sealed with a coded aluminium cap.

Pack sizes
Vaccine:
Cardboard box containing 1 or 10 vials of 500 or 1,000 doses.

Solvent (Dilavia):
Cardboard box containing 10 vials of solvent (100 or 200 ml) respectively.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/131/001

8. DATE OF FIRST AUTHORISATION

28 October 2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

05 September 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).