Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis CAV P4

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Vaccine:
Active ingredient:per dose of 0.2 ml
live attenuated CAA virus strain 26P4 ≥3.0 $\log_{10}TCID_{50}$

Solvent (Dilavia):
dl-α-tocopheryl acetate (adjuvant)
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (broiler breeders).

4.2 Indications for use, specifying the 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. Immunity has been demonstrated 6 weeks after vaccination. 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.

4.3 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.

4.4 Special warnings for each target species

Do not use in unhealthy birds. Sick or weak birds will not develop adequate immunity following vaccination.

The CAA vaccine virus has the ability to spread from vaccinates to susceptible birds. Care should be taken to avoid spread 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.

4.5 Special precautions for use

Special precautions for use in animals
None.

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

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interactions

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

Reconstitute the vaccine using the solvent provided, allowing 0.2 ml solvent per dose i.e. 200 ml per 1000 doses.
Administer 0.2 ml to every bird by intramuscular or subcutaneous injection. Equipment used for vaccination should be sterile and contain no traces of detergents or disinfectants.
Vaccination programme The optimum age and route (i.m. or s.c.) 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.

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

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

4.11 Withdrawal period(s)

Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Live attenuated vaccine which stimulates active immunity against CAV in order to provide passive immunity to the progeny.
QI01AD04

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine:
Pancreatic digest of casein, Dextran 70, Sorbitol, Sucrose, Gelatin, Dibasic potassium phosphate, Monobasic potassium phosphate.
Solvent:
dl-α-Tocopheryl acetate, Polysorbate 80, Monobasic potassium phosphate, Disodium phosphate dihydrate, Sodium chloride, Simethicone, Water for injections.

6.2 Major incompatibilities

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

6.3 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

6.4 Special precautions for storage

Vaccine: Store at 2-8°C.Do not freeze. Protect from light.
Solvent: Do not store above +25 °C. Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Vaccine:
Cardboard box containing 1 or 10 vials of 500 or 1,000 doses.
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):
Cardboard box containing 10 vials of solvent (100 or 200 ml) respectively.
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.
Not all presentations may be marketed.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/131/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 October 2003
Date of last renewal: 25 July 2008

10 DATE OF REVISION OF THE TEXT

February 2020