ΠΑΡΑΡΤΗΜΑ 1: ΠΕΡΙΛΗΨΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

---

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CAA Vaccine Nobilis

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF PRODUCT

Vaccine:

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

Diluent CAA:

dl-α-tocopherol acetate	75 mg/ml

3. PHARMACEUTICAL FORM

Lyophilisate and diluent for suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (broiler breeders).

4.2 Indications for use specifying the target species

To stimulate the production of antibodies to CAV in healthy broiler breeders.
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 Contra-indications

Do not use in sick or weak birds.
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

None

4.5 Special precautions for use

Special precautions for use in animals

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.
The freeze-dried plug must be reconstituted with the provided diluent only
Special precautions to be taken by the person administering the 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 safety and efficacy from concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with Nobilis CAV P4.

4.9 Amounts to be administered and administration route

Reconstitute the vaccine using the diluent provided, allowing 0.2 ml diluent 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 periods

Zero days

5. IMMUNOLOGICAL PROPERTIES

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

ATC code: QI01AD04

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stabiliser, buffer

6.2 Major incompatibilities

Do not mix with any other medicinal product apart from the diluent provided.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale

Vaccine

In freeze-dried form: 18 months (following up to 12 months storage by the manufacturer at -20°C)

Diluent

In glass bottles: 4 years

in PET bottles: 21 months.

Shelf life after dilution or reconstitution according to the directive
2 hours

6.4 Special precautions for storage

Vaccine: Store at +2°C to +8°C.
Diluent: Do not store above +25°C.

6.5 Nature and composition of immediate packaging

Cardboard box containing 1 or 10 vials of 500 or 1000 doses supplied with diluent (100 or 200 ml) respectively.
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.
CAA Diluent
Vial of hydrolytical type II glass (Ph.Eur.) or PET containing 100 or 200 ml diluent, 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 disposal of unused veterinary medicinal product or waste material 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 International B.V

8. MARKETING AUTHORISATION NUMBER

017955

9. DATE OF FIRST AUTHORISATION/FIRST RENEWAL OF AUTHORISATION

25/9/2008

10. DATE OF REVISION SPC OF THE TEXT

18/5/2010