

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Carton box/1,000 doses}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis CAV P4

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live freeze dried vaccine containing $\geq 3 \log_{10}$ TCID₅₀ Chicken Anaemia Agent per dose (0.2ml)

Reconstitute with the solvent provided before use.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension.

4. PACKAGE SIZE

1 vial with 1,000 doses.

5. TARGET SPECIES

Target species: Chickens.

6. INDICATION(S)

Lyophilisate for Suspension for I.M. or S.C. injection for chickens

To stimulate the production of antibodies to CAV in healthy broiler breeders.
Read package leaflet for directions and warnings before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: Intramuscular or subcutaneous injection.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store between +2°C and 8°C

Do not freeze. Protect from light. After reconstitution, use within 2 hours. Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

To be supplied only on veterinary prescription.

POM-VPS

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder in UK

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ
UK

MA holder in Ireland and distributor in Northern Ireland

Intervet Ireland Ltd.
Magna Drive, Magna Business
Park, Citywest Road, Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4322

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
{Label/1,000 doses}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis CAV P4
Lyophilisate for suspension for I.M. or S.C. Injection for Chickens

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ
UK

3. EXPIRY DATE

EXP end of: {month/year}

4. BATCH NUMBER

Lot: {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

Live freeze dried vaccine containing $\geq 3 \log_{10}$ TCID₅₀ Chicken Anaemia Agent per dose (0.2ml) Withdrawal period: Zero days. For animal treatment only.

Read package leaflet before use.

UK: POM-VPS

To be supplied only on veterinary prescription

Vm 01708/4322

Reconstitute with the solvent before use

Store between +2°C and 8°C

Do not freeze

Protect from light

Keep container in the outer carton

After reconstitution use within 2 hours

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

1. NAME OF THE DILUENT

Nobilis CAV P4 Solvent.
Adjuvanted solvent (dilavia).

The diluent contains dl- α -tocopherol acetate as an adjuvant.

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

10 x 200 ml

200 ml

3. ROUTES OF ADMINISTRATION

Read the instructions supplied with the vaccine carefully before use.

4. STORAGE CONDITIONS

Do not store above 25 °C. Reconstituted vaccine should be used within 2 hours. For animal treatment only. Keep out of the reach and sight of children.

5. BATCH NUMBER

Lot: {number}

6. EXPIRY DATE

EXP end of: {month/year}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

MA holder in the UK

MSD Animal Health UK Ltd. Walton Manor Walton Milton Keynes MK7 7AJ, UK.

MA holder in Ireland and distributor in Northern Ireland

Intervet Ireland Ltd. Magna Drive Magna Business Park Citywest Road Dublin 24
Ireland.

UK only

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Vm 01708/4322

PACKAGE LEAFLET FOR:

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

Marketing Authorisation holders

MSD Animal Health UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ
UK

Manufacturer responsible for batch release

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis CAV P4

Lyophilisate and solvent for suspension for injection

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

Vaccine: $\geq 3.0 \log_{10}$ TCID₅₀ live attenuated CAA virus strain 26P4 per dose of 0.2 ml
Solvent (Dilavia) contains dl- α -tocopherol acetate.

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

No clinical signs have been associated with an overdose of the vaccine. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (broiler breeders).

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

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 (IM or SC) 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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Vaccine: Store at 2 °C - 8 °C. Do not freeze. Protect from light. Solvent: Do not store above + 25 °C. Do not freeze. Protect from light. Keep out of the sight and reach of children. Shelf life after reconstitution: 2 hours Do not use after the shorter expiry date stated on the vaccine or solvent label.

12. SPECIAL WARNING(S)

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.

Use during lay

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

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

Wash and disinfect hands and equipment after vaccination

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.

Incompatibilities

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2021

15. OTHER INFORMATION

For animal treatment only.

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

ATC code: QI01AD04.

Sales presentation

Vaccine

Carton with 1 or 10 glass vials 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)

Carton with 10 vials of hydrolytical type II glass (Ph. Eur.) or PET containing 100 or 200 ml solvent, closed with halogenobutyl rubber bung (Ph. Eur.) and sealed with a coded aluminium cap.

Not all presentations may be marketed. To be supplied only on veterinary prescription.

UK only
Vm 01708/4322
POM-VPS

Distributor in Northern Ireland
Intervet Ireland Ltd. Magna Drive Magna Business Park Citywest Road Dublin 24
Ireland.

Approved 12 February 2021

A handwritten signature in black ink, consisting of a stylized initial followed by the name "Hunter." with a period.