

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton box (VIALS)}
Pet plastic box (CUPS)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Ma5+Clone 30 lyophilisate for oculonasal suspension/use in drinking water for chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Content per dose:

$\geq 10^{3.0}$ EID₅₀ of Infectious Bronchitis virus strain Ma5

$\geq 10^{6.0}$ ELD₅₀ of Newcastle Disease virus Clone 30

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension /use in drinking water for chickens.

4. PACKAGE SIZE

1 x 500 doses

1 x 1000 doses

1 x 2500 doses

1 x 5000 doses

1 x 10000 doses

10 x 500 doses

10 x 1000 doses

10 x 2500 doses

10 x 5000 doses

10 x 10000 doses

6 x 1000 doses

6 x 2500 doses

6 x 5000 doses

6 x 10000 doses

12 x 1000 doses

12 x 2500 doses

12 x 5000 doses

12 x 10000 doses

5. TARGET SPECIES

Target species: Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: spray, ocular use or drinking water administration. Read the package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. Protect from light.
Keep the container in the outer box.
Once reconstituted use within 2 hours.

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

Disposal: read package leaflet.

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

[Distribution category]

For animal treatment only.

POM-VPS

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

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

Distributor in Northern Ireland:

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

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4315

17. MANUFACTURER'S BATCH NUMBER

Batch No: {number}

To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – Lyophilisate CUPS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Ma5+Clone 30



2. QUANTITY OF ACTIVE SUBSTANCE

Live IB virus, Ma5

Live ND virus, Clone 30

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

1,000 doses (3-100 spheres)

2,500 doses (3-100 spheres)

5,000 doses (3-100 spheres)

10,000 doses (3-400 spheres)

4. ROUTE(S) OF ADMINISTRATION

See package leaflet.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER.

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Ma5+Clone 30

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose

≥ 10^{3.0} EID₅₀ of IB virus strain Ma5

≥ 10^{6.0} ELD₅₀ of ND virus strain Clone 30

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

500 doses,

1000 doses,

2500 doses,

5000 doses,

10000 doses

4. ROUTE(S) OF ADMINISTRATION

Route: spray, oculo-nasal instillation or drinking water administration.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

Expiry end of: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Target species: Chickens.

Once reconstituted use within 2 hours.

Withdrawal period: Zero days.

For animal treatment only.

Read package leaflet before use.

POM-VPS

Vm 01708/4315

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

PACKAGE LEAFLET FOR:

Nobilis Ma5+Clone 30

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

Marketing authorisation holder

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

Manufacturer for the batch release

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Ma5+Clone 30
Lyophilisate for oculonasal suspension/use in drinking water.

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

Content per dose

Live Infectious Bronchitis virus strain Ma5	$\geq 10^{3.0} \text{ EID}_{50}^*$
Live Newcastle Disease virus Clone 30	$\geq 10^{6.0} \text{ ELD}_{50}^{**}$

* egg infective dose 50%

** embryo lethal dose 50%

Vials: White/off-white coloured pellet.

Cups: White/off-white, predominantly spherical shaped.

4. INDICATION(S)

For the active immunisation of fowls against Massachusetts type or serologically related types of Infectious Bronchitis and against Newcastle Disease. Induction of active immunity of chickens, from one day-old onwards, against infectious bronchitis caused by Infectious Bronchitis Virus serotype Massachusetts and against infection with Newcastle Disease.

Duration of immunity: 6 weeks.

5. CONTRAINDICATIONS

Only healthy birds should be vaccinated. Sick or weak birds will not develop adequate immunity following vaccination.

6. ADVERSE REACTIONS

Slight respiratory reaction.

After administration of 100 doses only a slight reaction is observed.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens.

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

The vaccine is administered by (coarse) spray, oculonasal use or in the drinking water.

Administration by coarse spray or the oculo-nasal route is the method of choice when vaccinating young birds; fine spray for older birds.

The vaccine is safe to use from 1 day of age onwards.

The optimum time and method of administration depend largely on the local situation. Where necessary the advice of a veterinary surgeon should be sought.

The vaccine may be delivered as a freeze-dried cake in a glass vial or as freeze-dried spheres in cups. In case of the product presented in cups, do not use the product if the contents are brownish and stick to the container as this indicates that the integrity of the container has been breached. Each container should be used immediately and completely after opening.

The vials should be opened under water or the content of the cup(s) should be poured into the water. In both cases mix the water containing the vaccine well before use. After reconstitution the suspension looks clear.

Spray method

The vaccine should be dissolved in cool, clean water which is free of iron and chlorine. The appropriate number of vials should be opened under the surface of the water or the content of the cup(s) should be poured into the water. In both cases mix the water containing the vaccine well before use. After reconstitution the suspension looks clear. The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds. This will vary according to the age of the birds being vaccinated and the management system. The vaccine medicated

water should be spread evenly over the correct number of birds, at a distance of 30 - 40 cm. (12 - 16"), preferably when the birds are sitting together in dim light. The spray apparatus should be free from sediments, corrosion and traces of disinfectants (and ideally should be used for vaccination purposes only). Aerosol generators should be used only when it is known to be safe to the birds.

Number of doses	Day-old birds (Nozzle producing coarse droplets)	Older birds (Nozzle producing fine droplets)
1000	0.25 litre	1 Litre

Oculonasal use

Dissolve the vaccine in Nobilis Diluent Oculo/Nasal or physiological saline solution (usually 30 ml per 1000 doses) and administer by means of a standardised dropper. One drop should be applied from a height of a few centimetres onto one nostril or eye. The handler should ensure that the nasal drop is inhaled by the bird.

Drinking water

The vaccine is presented in vials under vacuum. The vials should be opened under water or the content of the cup(s) should be poured into the water. Measure the correct volume of water for the number of birds to be vaccinated (see below), add 20 gram skimmed milk powder or 500 ml liquid skimmed milk per 10 litre, allow to stand for 15 - 30 minutes, then open the correct number of vials of vaccine under the surface of the water (vials) or into the water (cups). All containers used should be clean and free from any traces of detergent or disinfectant. In both cases mix the water containing the vaccine thoroughly with a clean stirrer, ensuring that all containers used are emptied. After reconstitution the suspension looks clear. Offer to birds immediately and ensure uptake of all the vaccine medicated water in 2 hours. Use clean cold water, in which chlorine or metals can neither be tasted nor smelled. Where water sanitisers are used consult MSD technical staff. Only skimmed milk should be used, as the fat in whole milk may block the automatic drinking systems as well as reduce vaccine virus efficacy.

9. ADVICE ON CORRECT ADMINISTRATION

Volumes of water for reconstitution of vaccine

The volume of water for reconstitution depends on the age of the birds and the management practice.

Simple drinking troughs and fountains

The following are guidelines:

1000 doses / litre/ age in days up to a volume of 20 litre per 1000 doses.

For heavy breeds, or in hot weather, the quantity of water may be increased up to 30 litres per 1000 doses. Where the number of birds is between the standard dosages, the next higher dosage should be used.

Nipple Drinkers

Drinker line management is known to have a significant effect on the viability of live vaccine virus. The vaccine virus can deteriorate very rapidly, and it is essential to ensure that all birds received the correct dose.

Special care should be observed concerning the method of administration. For example, small header tanks may require recharging with medicated water several times during a 1 - 2-hour period.

Administration

Water should be withheld before vaccination. For recommendations see below under Management. Ensure that all medicated water is consumed within 1 - 2 hours. Turn on mains water when all the vaccine water has been consumed. Always make sure that there is food available when vaccinating.

Birds will not drink if they have no food to eat.

Management

Great care should be taken to ensure that all birds receive a full dose of vaccine when the product is administered in drinking water. When used in chickens where maternal antibody still exists, the way in which this vaccine is administered is critical. The following points have been found to improve vaccine "take":

1. Water withholding should be kept to a minimum, especially in broiler birds.

Approximately half an hour is all that is required if the following management techniques are used.

2. Try to vaccinate at a time when birds are likely to be drinking, e.g. morning time for broilers, when food is in the food tracks.

3. Turn the lights down low when the water is turned off. For bell drinkers, go round the house emptying and cleaning the drinkers during the half-hour lights low period. Mix up the vaccine according to the recommendations, and towards the end of the half-hour water withholding period, go round all the drinkers filling each with water containing vaccine. Leave the house and turn the light up. The increased light intensity will stimulate the birds to look for water and food. Therefore, it is important that food is available, or the birds will not be interested in drinking.

In some cases, it helps to run food tracks at the time the light intensity is increased. For nipple lines a substantial volume of residual water may remain in the lines after the half-hour water withholding/dark period. It is advisable to drain the lines and prime with vaccine loaded water before allowing the birds to have access to the drinker lines. Mix up the vaccine and apply to the header tank(s). Calculate the volume of water that is left in the tank below the outlet valve and make sure you add extra vaccine to this volume of water. For example, if 10 litres remain below the outlet pipe and you are using 10 litre/1000 birds to vaccinate, add one extra vial of vaccine when mixing up vaccine for that tank. The use of this extra vaccine is important.

4. Once the vaccine has been consumed, resume management practices as normal. This approach to vaccination will ensure a more even vaccination of the crop and will

be less stressful to the birds. Performance should therefore be less adversely affected.

For further information on use of a vaccine in specific circumstances or in conjunction with other MSD vaccines consult MSD technical staff.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Protect from light.

Keep the container in the outer box.

Shelf life after reconstitution according to the directive: 2 hours

Do not use after the expiry date stated on the label and carton.

12. SPECIAL WARNING(S)

The vaccine viruses spread rapidly to susceptible chicks.

Special precautions for use in animals

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. Under certain conditions, for example extreme disease pressure and variant challenge, fully immune birds may succumb to disease. Therefore, successful vaccination may not be synonymous with full protection in the face of a disease challenge.

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

Newcastle Disease Virus can cause transitory conjunctivitis in man. It is recommended to wear respiratory and eye protection in compliance with current European standards.

For more information contact the manufacturer.

Hands should be washed and disinfected after vaccinating.

Use during lay

Vaccination during the laying period may be accompanied by a transient drop in egg production.

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.

Do not mix with any other veterinary medicinal product.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2023

15. OTHER INFORMATION

For animal treatment only.

Pack sizes

Carton boxes containing 1 or 10 vials (type I glass) 500, 1000, 2500, 5000 or 10,000 doses of the vaccine.

PET plastic box with 6 cups of 1000 doses
PET plastic box with 6 cups of 2500 doses
PET plastic box with 6 cups of 5000 doses
PET plastic box with 6 cups of 10000 doses

PET plastic box with 12 cups of 1000 doses
PET plastic box with 12 cups of 2500 doses
PET plastic box with 12 cups of 5000 doses
PET plastic box with 12 cups of 10000
Not all pack sizes may be marketed.

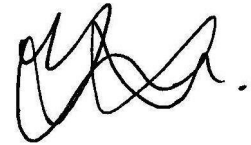
MA number Vm 01708/4315

POM-VPS

To be supplied only on veterinary prescription.

Distributor in Northern Ireland:

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

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 20 September 2023