

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard 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

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of reconstituted vaccine contains:

Avian infectious bronchitis virus (IBV), type Massachusetts, strain Ma5, Live:

≥ 3.0 log₁₀ EID₅₀

Newcastle disease virus (NDV), Clone 30, Live: ≥ 6.0 log₁₀ ELD₅₀

3. PACKAGE SIZE

1 x 500 doses
1 x 1000 doses
1 x 2500 doses
1 x 5000 doses
1 x 10 000 doses
10 x 500 doses
10 x 1000 doses
10 x 2500 doses
10 x 5000 doses
10 x 10 000 doses
6 x 1000 doses
6 x 2500 doses
6 x 5000 doses
6 x 10 000 doses
12 x 1000 doses
12 x 2500 doses
12 x 5000 doses
12 x 10 000 doses

4. TARGET SPECIES

Chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oculonasal use (incl. spray) or drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.

Do not freeze.

Protect from light.

Keep the container in the outer box.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 06376/4117

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS LABEL – Lyophilisate CUPS**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Ma5 + Clone 30



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1000 doses (6-100 spheres)
2500 doses (6-100 spheres)
5000 doses (6-100 spheres)
10 000 doses (6-400 spheres)

Live IBV, Ma5
Live NDV, Clone 30

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS
Glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Ma5 + Clone 30



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

500 doses
1000 doses
2500 doses
5000 doses
10 000 doses

Live IBV, Ma5

Live NDV, Clone 30

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each dose of reconstituted vaccine contains:

Active substances:

Avian infectious bronchitis virus (IBV), type Massachusetts, strain Ma5, live: $\geq 3.0 \log_{10} \text{EID}_{50}^*$
Newcastle disease virus (NDV), strain Clone 30, live: $\geq 6.0 \log_{10} \text{ELD}_{50}^{**}$

* EID_{50} = 50% Embryo Infective Dose

** ELD_{50} = Embryo Lethal Dose 50%

Lyophilisate:

Vials: White/off-white coloured pellet.

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

3. Target species

Chickens.

4. Indications for use

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

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

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.

The vaccine viruses spread readily to in contact chickens. Special precautions should be taken to avoid spreading of the vaccine strain to in contact chickens.

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

The application of the vaccine can cause temporary conjunctivitis in the operator. Avoid exposure to vaccine virus as much as possible.

Personal protective equipment consisting of respiratory and eye protection in compliance with current European standards should be worn when handling the veterinary medicinal product.

For more information contact the manufacturer.

Hands should be washed and disinfected after vaccinating.

Laying birds:

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

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.

Overdose:

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

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Respiratory signs ¹
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¹ Slight.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing

authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

At least 3.0 log₁₀ EID₅₀ (IB) and 6.0 log₁₀ ELD₅₀ (ND) per animal by:

- Spray vaccination
- Drinking water application
- Oculonasal application

The vaccine can be administered by (coarse) spray, by oculonasal use, or by in drinking water use. For oculonasal use a special solvent, Nobilis Diluent Oculo Nasal, is available.

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

The amount of volume used for application depends on the equipment used and the age of the animals to be vaccinated.

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 application

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 (preferably use it 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 one 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 grams skimmed milk powder or 500 ml liquid skimmed milk per 10 litres, 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. The vaccine should be dissolved in clean cold water, in which chlorine or metals can neither be tasted nor smelled. Where water sanitisers are used consult the marketing authorisation holder's 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.

The vaccine should be given in the early morning as this is the main period of drinking or the cool period on a hot day. When vaccinating larger flocks, it is advisable to start by dissolving only part of the vaccine. If vaccine is administered through a central water supply or a proportioner, great care should be taken. For numbers of birds between standard dosages, the next higher dosage should be chosen.

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 litres 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 litres/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 the marketing authorisation holder's technical staff.

10. Withdrawal periods

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 directions: 2 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Disinfect unused product and waste material by boiling or burning.

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/4117

Pack sizes:

Cardboard box containing 1 or 10 vials of 500, 1000, 2500, 5000 or 10,000 doses.

PET plastic box with 6 cups of 1000 doses, 2500 doses, 5000 doses or 10 000 doses.

PET plastic box with 12 cups of 1000 doses, 2500 doses, 5000 doses or 10 000 doses.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

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

Local representative:

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

Contact details to report suspected adverse reactions:

UK(GB)

MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

UK(NI)

Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-VPS

Gavin Hall
Approved: 10 October 2025