

NEW

Sphereon®  
technology, that only  
MSD Animal Health  
can provide.



**Increase your sphere of IB protection.**

**Nobilis® IB Primo QX**

Protectotype



**MSD**  
Animal Health

# Infectious Bronchitis QX.

Infectious bronchitis QX (otherwise known as D388) is a problem that originated in China, and spread to Europe in 2004 and over the last 10 years the QX strain of the virus has continued to spread throughout the world. The QX strain is particularly virulent and poses a real threat to flock health and subsequently has a significant impact on profitability.

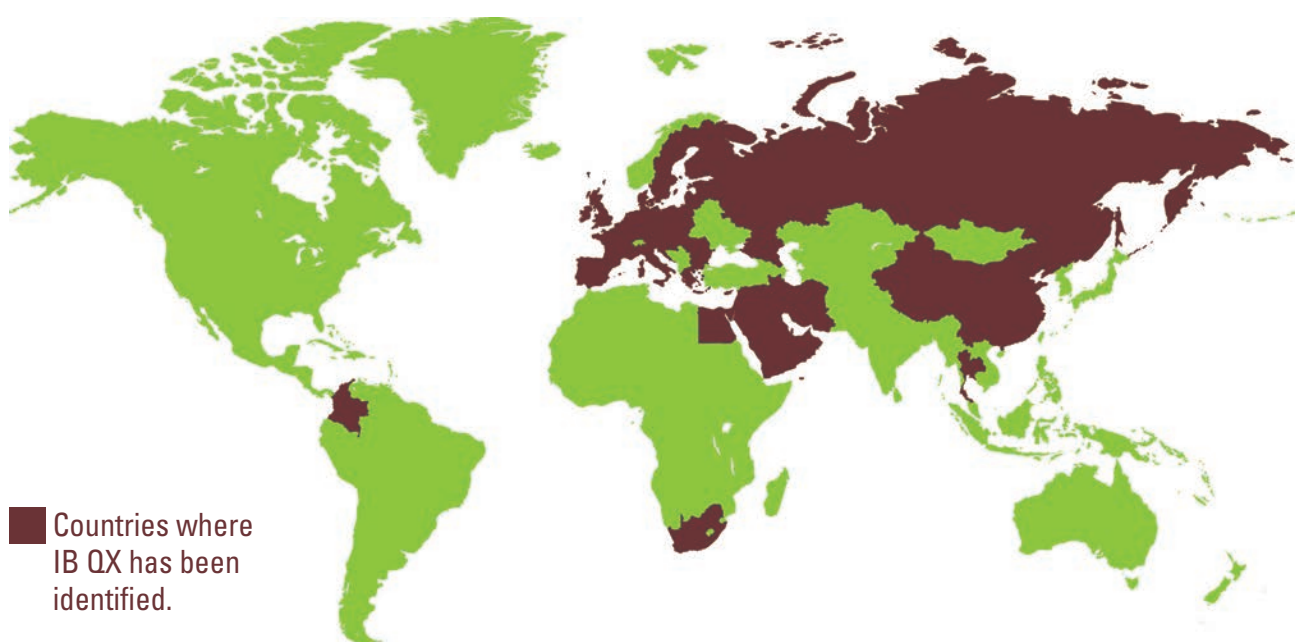
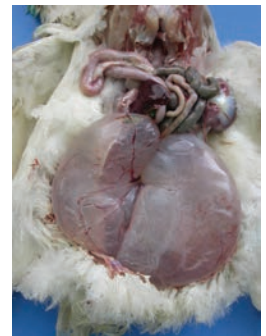
## The IB Virus

- The Infectious Bronchitis virus (IBV), a Coronavirus, targets not only the respiratory tract but also the urogenital tract.
- Kidney damage can also occur.
- Infection initially causes respiratory disease in the infected birds and also drops weight in broilers and egg production in layers and breeders.
- Control is best achieved by improved biosecurity and vaccination.
- The MSD Animal Health range of poultry vaccines, Nobilis®, has live and inactivated vaccines for the vaccination of breeder, layer and broiler chickens.

## The QX Strain

- IB QX serotype originated from China started really spreading around the globe around 2004.
- It is a typical IB disease affecting Breeders, Layers and Broilers.
- Clinical signs: Respiratory signs, kidney problems and egg production problems (numbers & egg quality) including “False Layer”.
- IBV results in serious performance losses - weight loss in broilers and lower egg production in layers & breeders.

Symptomatic “Penguin” shape associated with “False Layer” & post mortem examination. ►



# Nobilis® IB Primo QX.

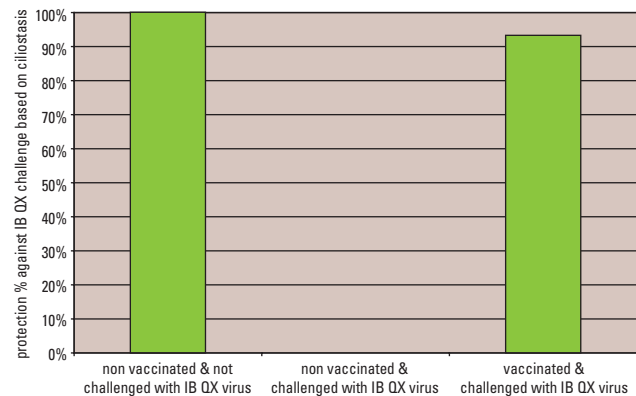
Nobilis® IB Primo QX completes the IB range offered by MSD Animal Health. The new vaccine has been developed to protect Breeders, Layers and Broilers from the IB QX strain and can be given at just one day old onwards.

## Features & Benefits

- Flexibility of application from one day old onwards.
- Hatchery application results in more accurate vaccination procedures and lower overall losses.
- Can be given by spray and eye/nose drop (intranasal/ocular route).
- Can be used with MA5 to complete the protectotype family - mix with Nobilis® IB Ma5 before ocular or spray administration. (Simultaneous use with Nobilis® IB Ma5).
- Indication for use: For the active immunization of chickens from one day-old onwards to reduce respiratory signs of IBV serotype D388/QX.
- Onset of immunity: 3 weeks.
- Duration of immunity: 8 weeks.
- Compatible with Nobilis® IB Ma5 from day one onwards.



Proven IB QX protection with Sphereon® technology.



## Sphereon® technology.

Sphereon® vaccines are live viral poultry vaccines packed in lightweight, easy to open aluminum cups. Sphereon® vaccines have exactly the same formulation as the Nobilis® line of vaccines in glass vials.

### Smart

- Colour coded labels: easy to recognise and helps to ensure the correct use of the vaccine.
- Each cup contains the exact number of Spheres required for optimum protection. The number of Spheres may vary per production batch.
- Lightweight aluminum cups are easy to transport, easy to store, easy to dispose of and easy to recycle.



### Simple

- Easy preparation of vaccine solution.
- No need to open vaccine under water, preventing contamination between operator hands and exposing the operator to live vaccines.
- Efficient large dose presentation sizes available.

### Soluble

- Fast and complete dissolving in water.
- Saves vaccine preparation time.
- Gives a uniform vaccination solution.



## Features & Benefits

- Flexibility of application from one day old onwards.
- Hatchery application results in more accurate vaccination procedures and lower overall losses.
- Can be given by spray and eye/nose drop (intranasal/ocular route).
- Can be used with MA5 to complete the protectotype family - mix with Nobilis® IB Ma5 before oculonasal or spray administration. (Simultaneous use with Nobilis® IB Ma5).
- Indication for use: For the active immunization of chickens from one day-old onwards to reduce respiratory signs of IBV serotype D388/QX.
- Onset of immunity: 3 weeks.
- Duration of immunity: 8 weeks.
- Compatible with Nobilis® IB Ma5 from day one onwards.

## Recommendations

- Store the vaccines at a temperature of 2°C - 8°C.
- Always use clean vaccine material.
- Check the insert leaflet for product specific recommendations.
- Do not use the vaccine if the spheres are floating in the water.
- Exactly the correct number of spheres is added for optimum protection. The number of spheres can vary from production batch to production batch.
- Each cup should be used immediately after opening and emptied completely in the vaccine solution.
- Do not use the vaccine if the cup has been opened before and the spheres appear to be shrunk and dehydrated.

## Nobilis® IB Primo QX

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT: Marketing authorisation holder and manufacturer for batch release: Intervet International B.V. Wim de Kierverstraat 35, 5831 AN Boxmeer, The Netherlands 2. NAME OF THE VETERINARY MEDICINAL PRODUCT: Nobilis IB Primo QX lyophilisate and solvent for suspension for chicken, Nobilis IB Primo QX lyophilisate for suspension for chicken, Nobilis IB Primo QX lyophilisate for suspension for chicken. 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S): Each dose of reconstituted vaccine contains: Live attenuated avian infectious bronchitis virus, strain D388; 104.0 – 105.5 EID50/1. 1 50% egg infective dose. Lyophilisate: Off white, predominantly sphere shaped. Solvent (Solvent Oculo/Nasal): blue-coloured solution. 4. INDICATION: For active immunisation of chickens in order to reduce respiratory signs of avian infectious bronchitis caused by QX-like variants of infectious bronchitis virus (IBV). Onset of immunity: 3 weeks. Duration of immunity: 8 weeks. 5. CONTRAINDICATIONS: Do not use in laying birds or within 4 weeks before the onset of the laying period. 6. ADVERSE REACTIONS: After vaccination a mild transient respiratory reaction (including nasal exudates) may occur for at least 10 days, these reactions are very rare. The frequency of adverse reactions is defined using the following convention: very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment), common (more than 1 but less than 10 animals in 100 animals), uncommon (more than 1 but less than 10 animals in 1,000 animals), rare (more than 1 but less than 10 animals in 10,000 animals), very rare (less than 1 animal in 10,000 animals, including isolated reports). 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: After reconstitution, administer 1 dose of vaccine by coarse spray or by the oculonasal route of administration to chickens from 1 day of age or older. Cups may contain 3 spheres to up to 400 spheres depending on the required dosages and production yields. 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. 9. ADVICE ON CORRECT ADMINISTRATION: Reconstitute the lyophilisate immediately and entirely after opening of the cup. Administration routes: Spray vaccination: When spray devices are used it is advisable to consult the technical staff of the distributors before using this technique. Apply coarse spray ~250 microns. All containers used for reconstitution should be clean and free from any traces of detergent or disinfectant. (1) Reconstitute the lyophilisate using water of good quality (e.g. free from chlorine and/or disinfectants). Measure the correct volume of water for the number of birds to be vaccinated (depends on devices used). (2) Add the contents of the cup while stirring. (3) Mix thoroughly with a clean stirrer, ensuring that all vaccine is solved. After reconstitution the suspension looks clear. (4) Offer to birds immediately. Oculonasal administration: Solvent Oculo/Nasal is available as solvent for oculonasal application. (1) The contents of a cup (1,000 doses only) can be added to Solvent Oculo/Nasal using the included adapter and administered after connecting the included dropper. (2) Shake the vaccine suspension. After reconstitution the suspension looks clear. (3) One drop containing one dose should be applied into one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the bird. 10. WITHDRAWAL PERIOD: Zero days. 11. SPECIAL STORAGE PRECAUTIONS: Keep out of the sight and reach of children. Lyophilisate: Store in a refrigerator (2 °C – 8 °C). Do not freeze. Protect from light. Solvent: Store below 25 °C. Do not freeze. Do not use this veterinary medicinal product after the expiry date which is stated on the label. Shelf life after reconstitution according to directions: 2 hours. 12. SPECIAL WARNING(S): Special warnings for each target species: The vaccine virus is capable of spreading to animals for a minimum of 20 days after vaccination and appropriate care should be taken to separate vaccinated from non-vaccinated chickens. Precautionary measures should be taken to prevent spreading to wildlife. The premises must be cleaned and disinfected after each production round. This vaccine should only be used after it has been established that the QX-like IBV variant strain is epidemiologically relevant. It is important to avoid introduction of the IB D388/QX vaccine virus into premises in which the wild type strain is not present. The IB D388/QX vaccine should only be applied in hatcheries if adequate controls are in place to avoid the spread of the vaccine virus to birds that will be transported to non-IB QX exposed flocks. The vaccine has been demonstrated to provide protection against QX-like variant. The protection against other circulating IB strains has not been investigated. Special precautions for use in animals: Vaccinate only healthy chickens. All chickens on the site should be vaccinated at the same time. Special precautions to be taken by the person administering the veterinary medicinal product to animals: In case of spray administration, personal protective equipment consisting of masks with eye protection should be worn when handling the veterinary medicinal product. Wash and disinfect hands and equipment after vaccination to avoid the spread of the virus. Lay: The safety and efficacy of the veterinary medicinal product has not been established during lay. Do not use in laying birds and within 4 weeks before the onset of the laying period. Interaction with other medicinal products and other forms of interaction: Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Nobilis IB Ma5 for spray or oculonasal application. Simultaneous use of both vaccines increases the risk of recombination of viruses and potential emergence of new variants. However, the chance of a hazard occurring has been estimated very low. For the mixed products the onset of immunity is 3 weeks and the duration of immunity is 8 weeks for the claimed protection against Massachusetts and QX-like strains of IBV. The safety parameters of the mixed vaccines are not different from those described for the vaccines administered separately. Read the package leaflet of Nobilis IB Ma5 before use. No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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 (symptoms, emergency procedures, antidotes): Very mild inflammatory changes have occasionally been found in the kidneys of specific pathogen free (SPF) chickens after administration of a 10 fold overdose. Incompatibilities: Do not mix with any other veterinary medicinal product, except Nobilis IB Ma5 or Solvent Oculo/Nasal recommended for use with the veterinary medicinal product. 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY: Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment. 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED: Detailed information on this product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>). 15. OTHER INFORMATION: Nobilis IB Primo QX is intended to protect chickens against clinical signs of disease caused by IBV variant strain D388 only and should not be used as a replacement for other IBV vaccines. Chickens should be vaccinated against other prevalent IBV serotypes (e.g. Massachusetts) according to the local IB vaccination programme. Packaging: Cardboard box with 10 cups of lyophilisate (1,000 doses per 42 mm diameter cup), Cardboard box with 10 cups of lyophilisate (5,000 doses per 42 mm diameter cup), Cardboard box with 10 cups of lyophilisate (10,000 doses per 61 mm diameter cup), Cardboard box with 10 vials of solvent (35 ml vials) supplemented with dropper and adapter. Not all pack sizes may be marketed. For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

For more information contact your local MSD Animal Health representative.

MSD Animal Health - Optimising vaccine performance through partnership & support.

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**Protectotype**



Find out more.



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## Application Guide.

- 1 Open the seal of the Sphereon® cup.
- 2a Empty the Sphereon® vaccine via the funnel into the diluent for eye-drop application.
- 2b Pour the vaccine in the water for spray administration.
- 3 Stir/shake the vaccine solution.
- 4 Administer the vaccine.

