Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Rhino CV.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Per dose min. $10^{1.5}$ $TCID_{50}$* and max. $10^{3.7}$ $TCID_{50}$ of live attenuated avian rhinotracheitis virus strain 11/94.

For a list of excipients, see section 6.1.

* Tissue Culture Infective Dose 50%

3 PHARMACEUTICAL FORM

Lyophilisate for suspension for oculonasal or spray application.

4 CLINICAL PARTICULARS

4.1 Target Species

Chicken.

4.2 Indications for use, specifying the target species

For broilers, future layers and breeders from one day of age.

Broilers, future layers and breeders
Active immunisation in order to reduce the frequency and the severity of clinical signs due to infection with avian rhinotracheitis virus (avian metapneumovirus). The onset of immunity is 3 weeks and the duration of immunity is 16 weeks post-vaccination.

Future layers and breeders
Priming with Nobilis Rhino CV, followed by a second vaccination with an inactivated vaccine containing the avian rhinotracheitis virus strain But1#8544 before the onset of lay results in a reduction of the clinical signs including egg drop, caused by infection with avian rhinotracheitis virus. Protective immunity is maintained for the normal laying period.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Only vaccinate healthy birds.
In order to reduce the circulation of the vaccine strain, all susceptible animals on the site have to be vaccinated properly and preferably at the same time. The vaccine virus can spread to other susceptible species with which they have direct contact. It was shown that the spreading has negligible impact on turkeys, which together with chickens constitute the species that are most susceptible to avian rhinotracheitis virus.

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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

In a low percentage of flocks (less than 10 %), vaccination can lead to slight nasal discharge or coughing by some birds between 2 to 7 days after administration for 1 to 2 days.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay and/or within 4 weeks before the onset of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with vaccines against infectious bronchitis containing strain H120 and against Newcastle disease containing strains Clone 30 or C2 and infectious bronchitis vaccine (strain IB Ma 5) when given on day 1 (the efficacy of the IB Ma5 vaccine has not been investigated).

Intervet’s live vaccine against Gumboro disease (infectious bursal disease) containing the D78 strain can be given 7 days after Nobilis Rhino CV.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above.
A decision to use this vaccine before or after any other veterinary product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Oculonasal administration via eye- or nose-drop method or via coarse spray, one dose per bird from 1 day old.

Oculonasal route
Reconstitute the freeze-dried vaccine in clean, disinfectant- and antiseptic-free water to which 2% liquid skimmed milk is added and administer by means of a standardised dropper. The amount of fluid required for eye- or nose-drop administration depends on the number of doses and the droplet size, but approximately 35 ml per 1000 doses is used. Apply one drop in a nare or eye. Check that the drop is entirely absorbed before releasing the bird.

Spray vaccination
The vaccine must be reconstituted with clean, disinfectant- and antiseptic-free water to which 2% of liquid skimmed milk is added. The appropriate number of vials must be opened under water. The volume of vaccine suspension must be sufficient to ensure a homogeneous vaccination of the birds.
Depending on the age of the chickens to be vaccinated and the rearing system, take 250 to 500 ml of water per 1000 doses. The vaccine suspension is to be sprayed evenly over the appropriate number of animals at a distance of 30-40 cm with a regular spraying apparatus, preferably when the animals sit together under a dim light. The spray apparatus must be free from sediments, corrosion and traces of disinfectants and ideally should be used for vaccination purposes only.
If applicable, reduce ventilation to prevent loss of spray.

For future layers and breeders please see section 4.2.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Administration of tenfold the maximum dose by the recommended routes has not resulted in any other effect on the target species than those described under 4.6.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The vaccine contains the live attenuated strain 11/94 of avian rhinotracheitis virus, sub-type B. Upon administration, the vaccine induces active immunity in chickens against avian rhinotracheitis virus.
The growth characteristic of the vaccine strain in Chicken Embryo Fibroblasts allows differentiation from field virus. Indicative results can be obtained by specialised laboratories.
ATC Vet code: QI01AD01. Avian Rhinotracheitis virus vaccine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pancreatic digest of casein
Sorbitol
Gelatine
Disodium phosphate dihydrate
Water for injections

6.2 Incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

Store in a refrigerator (+2°C to +8°C).
Do not freeze
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Cardboard box containing 1, 2, 5, 10, 20 or 50 glass (Type I) vials of 250, 500, 1000, 2500, 5,000, 10,000 or 25,000 doses closed with a halogenobutyl rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/190/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16th June 2010

10 DATE OF REVISION OF THE TEXT