Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Diluent Oculo Nasal

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances:
None

Excipients:
Patent Blue V (E131) 0.17 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Diluent for oculo nasal use.
Clear, blue coloured solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Poultry

4.2 Indications for use, specifying the target species

Diluent for reconstitution of Nobilis live freeze-dried vaccines licensed for oculonasal administration to poultry.

4.3 Contraindications

Any contraindications specified for the vaccine for which the diluent is used for reconstitution will apply.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
No special precautions are required for handling the diluent however any recommendations specified for the vaccine for which Nobilis Diluent Oculo Nasal is used as a diluent will apply.

Special precautions to be taken by the person administering the product to animals
None.

4.6 Adverse reactions (frequency and seriousness)

Any adverse effects specified for the vaccine for which Nobilis Diluent Oculo Nasal is used as the diluent will apply.

4.7 Use during pregnancy, lactation or lay

Any recommendations specified for the vaccine for which Nobilis Diluent Oculo Nasal is used as the diluent will apply.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

The instructions supplied with the vaccine should be read carefully before using the diluent.
For freeze dried vaccines the contents of the diluent vial should be transferred aseptically into the vial of freeze-dried vaccine immediately prior to use.

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

No specific treatment or antidote recommended.

4.11 Withdrawal Period(s)

Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Not applicable. The diluent does not contain active ingredients.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Sodium chloride
Disodium edetate (EDTA)
Patent Blue V (E131)
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product except the vaccines recommended for use with the product.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years

Shelf life after first opening of the container: Use immediately after opening

6.4 Special precautions for storage

Do not store above 25°C
Keep the container in the outer carton

6.5 Nature and composition of immediate packaging

The product is supplied in cartons with 10 PET vials containing 31.5 or 79 ml closed with a halogenated butylrubber stopper and an aluminium crimp cap. Cartons contain 10 x 31.5 ml vials or 10 x 79 ml vials.
31.5 ml vial contains diluent for 1000 vaccine doses.
79 ml vial contains diluent for 2500 vaccine doses.
Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of 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 10996/203/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17th August 2012

10 DATE OF REVISION OF THE TEXT