Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Ducat

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Per dose of 1 ml reconstituted vaccine:
Live attenuated feline viral rhinotracheitis virus, strain G2620A at least 4.8 $\log_{10}$ $TCID_{50}$ *,
Live attenuated feline calicivirus, strain F9 at least 4.6 $\log_{10}$ PFU**.

* tissue culture infectious dose
** plaque forming units

Excipient(s):
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cats

4.2 Indications for use, specifying the target species

Active immunisation of cats against feline viral rhinotracheitis (feline herpes virus type I) and feline calicivirus infections. Vaccination reduces clinical signs caused by these viral infections.
Onset of immunity: 4 weeks
Duration of immunity: 1 year.

4.3 Contraindications

See section 4.7.

4.4 Special warnings for each target species

Vaccination at six weeks of age has been proven to be safe.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate only healthy animals. Care should be taken that aerosol is not formed when vaccinating the cat as nasal or oral exposure could result in clinical respiratory signs including lethargy and malaise. For the same reason, the cat should be prevented from licking the injection site.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A slight transient, sometimes painful, swelling (≤ 5mm) may be observed at the site of injection for one day. A slight temporary rise in rectal temperature may occur, while occasionally transient lethargy may be observed during the first day after vaccination. In rare cases the vaccine may cause hypersensitivity reactions (pruritis, dyspnoea, vomiting, diarrhoea and collapse).

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy and lactation as the product has not been tested in pregnant and lactating queens.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other, except Intervets' vaccine containing rabies antigen, strain Pasteur RIV, where this product and the combined use is authorised. A decision to use Nobivac Ducat before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Allow the sterile diluent provided to reach room temperature. Aseptically reconstitute the lyophilised vaccine with one ml of the diluent. Shake well after addition of the diluent. One ml of the reconstituted vaccine should be given by subcutaneous injection.

- Basic vaccination: cats from 8 weeks of age onwards should receive two vaccinations with an interval of 3-4 weeks.
- Revaccination: annual booster

In the initial vaccination course, Intervets' vaccine containing rabies antigen, strain Pasteur RIV, may be used to reconstitute Nobivac Ducat at the vaccination at 12 weeks of age (where this product and the combined use is authorised).

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

A transient swelling (≤ 5mm) at the injection site may occur for four to ten days. A transient increase in temperature (<40.8°C) may occur while occasionally lethargy for one day after vaccination may be observed.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Live viral vaccine.
ATC vet code: QI06AD03
To stimulate active immunity against feline rhinotracheitis virus and feline calici virus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin-based stabiliser
Phosphate buffer
Sucrose
Water for injections

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product except the diluent supplied with the product or with Intervets' vaccine containing rabies antigen, strain Pasteur RIV (where this product and the combined use is authorised).

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after reconstitution according to directions: 30 minutes

6.4 Special precautions for storage

Vaccine: Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light.
Solvent: Store below 25°C if stored independently from the vaccine.

6.5 Nature and composition of immediate packaging

Vaccine:
Vial of hydrolytical class type I (Ph. Eur.) glass. The vial is closed with a halogenobutyl rubber bung and sealed with a coded aluminium cap.

Solvent:
Vial of hydrolytical class type I (Ph. Eur.) glass. The vial is closed with a halogenobutyl rubber bung and sealed with a coded aluminium cap.

Pack sizes: Carton or plastic-boxes with 5, 10, 25 or 50 doses of vaccine and solvent.
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 10996/182/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th January 2005
Date of last renewal: 21st August 2009

10 DATE OF REVISION OF THE TEXT

October 2014