

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Forcat.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml:

Lyophilisate:

Active substances:

- live attenuated feline calicivirus, strain F9: $\geq 4.6 \log_{10}$ PFU¹;
- live attenuated feline herpes virus type 1, strain G2620A: $\geq 5.2 \log_{10}$ PFU¹;
- live attenuated feline panleucopenia virus, strain MW-1: $\geq 4.3 \log_{10}$ CCID₅₀²;
- live attenuated *Chlamydophila felis*, strain Baker: $\geq 2.3 \log_{10}$ CCID₅₀².

¹PFU: Plaque-Forming Units

²CCID₅₀: Cell Culture Infective Dosis 50%

Excipients:

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:

- to reduce the clinical signs caused by infection with feline calicivirus and feline herpes virus type 1,
- to reduce the severity of the clinical signs caused by infection with *Chlamydophila felis*,
- to prevent the clinical signs, leucopenia and virus excretion caused by infection with feline panleucopenia virus.

Onset of immunity: for FCV and FHV: 4 weeks; for FPLV and *C. felis*: 3 weeks.

Duration of immunity for FCV, FHV, *C. felis*: 1 year, for FPLV: 3 years.

4.3 Contraindications

See point 4.7.

4.4 Special warnings for each target species

Because antimicrobials may inactivate the live *C. felis* vaccine strain, systemic antimicrobial therapy should be avoided during vaccination and for a two week period afterwards.

Maternal antibodies, which may persist up to the age of 9-12 weeks, can have a negative influence on the efficacy of vaccination. In the presence of maternal antibodies, vaccination may not completely prevent the clinical signs, leucopenia and virus excretion following an FPLV infection, and may reduce the protection against a *C. felis* infection. In such cases where a high level of maternally derived antibodies is expected, the vaccination schedule should be planned accordingly.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.

The *C. felis* vaccine strain may be excreted by vaccinated cats for more than 21 days and may be transmitted to non-vaccinated animals without inducing clinical signs.

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

It is advised that immunodeficient persons or persons taking immunosuppressive drugs do not handle this vaccine. Owners should be made aware that some vaccinated cats may excrete *C. felis*.

In case of accidental self injection, seek medical advice immediately and show the package leaflet or the label to the physician, referring to the live chlamydial component.

4.6 Adverse reactions (frequency and seriousness)

A slight painful swelling may be observed at the injection site for 1-2 days. A slight transient rise in body temperature (up to 40°C) may occur for 1-2 days. In some cases sneezing, coughing, nasal discharge, and a slight dullness or reduced appetite may be observed for up to 2 days post vaccination.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy or lactation, as the product has not been tested in pregnant or lactating queens. Live FPL virus can cause reproductive problems in pregnant queens and birth defects in the progeny.

4.8 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.

4.9 Amounts to be administered and administration route

Use 1 ml solvent to reconstitute the lyophilisate (= 1 single dose).
Administer 1 ml of the vaccine per animal by subcutaneous injection.
Use sterile injection equipment, free from traces of disinfectants.

Vaccination schedule:

Basic vaccination:

Two single dose inoculations, 3-4 weeks apart.

The first inoculation can be given from the age of 8-9 weeks and the second inoculation from the age of 12 weeks. (See also section 4.4)

Revaccination:

A single dose (1 ml) according to the following schedule:

Revaccination against feline calicivirus, feline herpesvirus type 1 and *Chlamydophila felis* must be given every year (with Nobivac Forcat or other vaccines containing the F9, G2620 or Baker strains, where available).

Revaccination against feline panleucopenia virus can be given every three years (with strain MW-1 as in Nobivac Forcat, where available).

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

At ten-fold overdose, a slight painful swelling may be observed at the injection site for 4-10 days.

A slight transient rise in temperature (up to 40.8°C) may occur for 1-2 days.

In some cases general discomfort, coughing, sneezing, transient lethargy and reduced appetite may be observed for a few days post vaccination.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live bacterial and viral vaccine for cats

ATCvet code: QI06AF01

To stimulate active immunity against feline calicivirus (FCV), feline herpesvirus type 1 (FHV, feline rhinotracheitis virus), feline panleucopenia virus (FPL) and *Chlamydophila felis* (formerly called feline *Chlamydia psittaci*) in cats.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate

Gelatin

Sucrose

Disodium phosphate dihydrate

Solvent

Disodium phosphate dihydrate

Potassium dihydrogen phosphate

Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product, except diluent supplied for use with the product.

6.3 Shelf-life

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

- Lyophilisate: 33 months.

- Solvent: 5 years

Shelf life after reconstitution according to directions: 30 minutes.

6.4 Special precautions for storage

–Lyophilisate: Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light.

–Solvent: Store below 25°C if stored separately from the lyophilisate. Do not freeze.

6.5 Nature and composition of immediate packaging

– Lyophilisate: 1 dose vial of glass type I (Ph.Eur.) closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

– Solvent: 1 dose vial of glass type I (Ph.Eur.) closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Pack sizes:

Solvent may be packed together with the lyophilisate or separately:

Carton box with 5 doses of lyophilisate and solvent

Carton box with 10 doses of lyophilisate and solvent

Carton box with 25 doses of lyophilisate and solvent

Carton box with 50 doses of lyophilisate and solvent

Carton box with 5 doses of lyophilisate and carton box with 5 doses of solvent

Carton box with 10 doses of lyophilisate and carton box with 10 doses of solvent

Carton box with 25 doses of lyophilisate and carton box with 25 doses of solvent

Carton box with 50 doses of lyophilisate and carton box with 50 doses of 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 approved for use by the competent authorities.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive,
Magna Business Park,
Dublin 24,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/195/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20th December 2010

10 DATE OF REVISION OF THE TEXT