1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Solvent

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

None.

Excipients:

Qualitative composition of excipients and other constituents
Disodium phosphate dehydrate
Potassium dihydrogen phosphate
Water for injections

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats and dogs.

3.2 Indications for use for each target species

Solvent for reconstitution of Nobivac DHP, Nobivac DHPPi, Nobivac Parvo-C, Nobivac Ducat,Nobivac Tricat Trio vaccines and Nobivac Pi.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

No special precautions are required for handling the solvent however any recommendations specified for the vaccine for which Nobivac Solvent is used as a solvent will apply.

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 leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Any adverse effects specified for the vaccine for which Nobivac Solvent is used as the solvent will apply.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Any recommendations specified for the vaccine for which Nobivac Solvent is used as the solvent will apply.

3.8 Interaction with other medicinal products and other forms of interaction

None known for the solvent, however any recommendations specified for the vaccine for which Nobivac Solvent is used as the solvent will apply.

3.9 Administration routes and dosage

Subcutaneous use.
The instructions supplied with the vaccine should be read carefully before using the diluent. The contents of one vial of Nobivac Solvent (1 ml) should be transferred aseptically into the vial of freeze-dried vaccine immediately prior to use. Care should be taken to ensure that the freeze-dried powder plug has fully dissolved.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Any information or recommendations specified for the vaccine for which Nobivac Solvent is used as the solvent will apply.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL or IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: : QV07AB

The solvent does not contain active ingredients. The solvent alone does not have immunological properties.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.
The solvent should only be mixed with the products listed in section 3.2.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 48 months.
Shelf life after first opening the immediate packaging: Use immediately.

5.3 Special precautions for storage

Do not store above 25 °C.
Do not freeze.
Protect from light.
Keep the vial in the outer carton.

5.4 Nature and composition of immediate packaging

Clear, glass Type I (Ph.Eur) single vials with halogenobutyl rubber stopper and aluminium crimp cap.

Pack sizes
Nobivac Solvent packed separately from the Nobivac vaccine for which it is authorised:
Carton or plastic box with 10 x 1 ml or 50 x 1 ml.

Nobivac Solvent packed with the Nobivac vaccine for which it is authorised:
Carton or plastic box with 5 x 1 dose vials of Nobivac vaccine and 5 x 1 ml Nobivac Solvent .
Carton or plastic box with 25 x 1 dose vials of Nobivac vaccine and 25 x 1 ml Nobivac Solvent.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/177/001

8. DATE OF FIRST AUTHORISATION

03/10/2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

03/03/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).