SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE PRODUCT

Nobivac Solvent

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF PRODUCT

Active ingredient **per 1 ml**
Not applicable.

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

A clear colourless liquid solvent for parenteral use, consisting of sterile phosphate-buffered water presented in single 1 ml vials.

4. CLINICAL PARTICULARS

4.1 Target species

Cats and dogs.

4.2 Indications for use specifying the target species

To reconstitute freeze dried small animal Nobivac vaccines which include instructions to be reconstituted with Nobivac Solvent.

4.3 Contraindications

Any contra-indications specified for the vaccine for which the Nobivac Solvent is used for reconstitution will apply.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

Special precautions for use in animals

No special precautions are required for handling the solvent however any recommendations specified for the vaccine for which Nobivac Solvent is used for reconstitution will apply.
Sterile equipment should be used for administration. Avoid contamination of vaccine

with traces of chemical sterilising agents. Do not use chemicals such as disinfectant or spirit to disinfect the skin prior to inoculation.

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.
After reconstitution: Any recommendations specified for the vaccine for which Nobivac Solvent is used for reconstitution will apply.

4.6 Adverse reactions (frequency and seriousness)

Any adverse reaction specified for the vaccine for which Nobivac Solvent is used for reconstitution will apply.

4.7 Use during pregnancy, lactation and lay

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

4.8 Interaction with other medicaments and other forms of interaction

Solvent should only be used for the reconstitution of Nobivac small animal vaccines which have specific instructions for use with Nobivac Solvent.
No information is available on the safety and efficacy when used with any other veterinary medicinal product. Any recommendations specified for the vaccine for which Nobivac Solvent is used for reconstitution will apply.

4.9 Amounts to be administered and administration route

The instructions supplied with the vaccine should be read carefully before using the Nobivac Solvent.
The contents of one vial (1 ml) of Nobivac Solvent 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.

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

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

4.11 Withdrawal periods

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Not applicable. The diluent does not contain active ingredients.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium di-hydrogen phosphate
di-Sodium phosphate
Water for injections

6.2 Incompatibilities

For use only with Intervet freeze-dried small animal vaccines which have specific instructions for reconstitution with Nobivac Solvent. Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze. Protect from light.

6.5 Nature and composition of immediate container

Clear, Glass Type I (Ph.Eur) single vials with halogenobutyl rubber stopper (Ph.Eur.) and aluminium crimp cap.
Pack size: Boxes with 10 x 1 ml or 50 x 1 ml vials.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Solvent only: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

After reconstitution: Any recommendations specified for the vaccine for which Nobivac Solvent is used will apply.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

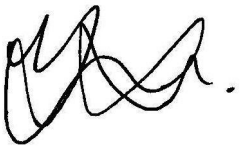
Vm 01708/4368

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

November 2020



Approved: 05 November 2020