PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Solvent

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each single dose vial contains 1 ml of sterile phosphate buffered solvent.

3. PHARMACEUTICAL FORM

Solvent for parenteral use

4. PACKAGE SIZE

10 x 1 ml
50 x 1 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Method, route of administration, warnings and disposal advice: **Read package leaflet before use**.
Read the instructions supplied with the vaccine carefully before using this solvent.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

SECTIONS 10 – 17 ARE PRINTED ON THE SEAL

10. EXPIRY DATE

EXP end of: {month/year}
Once broached, use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.
POM-V
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4368

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT/SOLVENT LABEL

GLASS VIAL - solvent

1. NAME OF THE DILUENT/SOLVENT

Nobivac Solvent
– sterile buffered solution

2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

3. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store below 25 °C.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp. {mm/yyyy}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health logo

PACKAGE LEAFLET FOR:

Nobivac Solvent

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Solvent

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

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

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Read the instructions supplied with the vaccine carefully before using 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C.
Do not freeze.
Protect from light.
Keep the vials in the outer box.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and outer box after 'EXP end of'.

12. SPECIAL WARNING(S)

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.

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.

Interaction with other medicinal products 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.

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

Overdose (symptoms, emergency procedures, antidotes)
Any recommendations specified for the vaccine for which Nobivac Solvent is used for reconstitution will apply.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2023

15. OTHER INFORMATION

For animal treatment only.

Pack sizes:
Boxes with 10 x 1 ml or 50 x 1 ml vials.
Not all pack sizes may be marketed.

Vm 01708/4368

POM-V To be supplied only on veterinary prescription.

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

Distributor in Northern Ireland
Intervet Ireland Ltd., Magna Drive, Magna Business Park
Citywest Road, Dublin 24, Ireland

Approved: 12 June 2023