

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Unisolve

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Does not contain active components.

Aqueous solution containing phosphate buffered saline and sucrose.

3 PHARMACEUTICAL FORM

Solvent for parenteral or intranasal use.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep, cattle and poultry

4.2 Indications for use, specifying the target species

Solvent for reconstitution of Toxovax, Enzovax, Bovilis IBR marker live and Nobilis Marek THV Iyo vaccines.

4.3 Contraindications

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

4.4 Special warnings for each target species

There are no special warnings, however any warnings specified for the vaccine for which Unisolve is used as the solvent will apply.

4.5 Special precautions for use

Special precautions for use in animals

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

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

There are no special precautions, however any precautions specified for the vaccine for which Unisolve is used as the solvent will apply.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

No interactions are known for the solvent, however any recommendations specified for the vaccine for which Unisolve is used as the solvent will apply.

4.9 Amounts to be administered and administration route

The instructions supplied with the vaccine should be read carefully before using the solvent. For lyophilised vaccines the contents of the solvent vial should be transferred aseptically into the vial of lyophilised vaccine immediately prior to use. In the case of Toxovax the vaccine concentrate should be added to the solvent vial in accordance with the instructions provided.

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

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

4.11 Withdrawal Period(s)

The withdrawal period specified for the vaccine for which Unisolve is used as the solvent will apply.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Not applicable. The solvent does not contain active ingredients.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Disodium Phosphate Dihydrate
Potassium Dihydrogen Phosphate
Sodium Chloride
Water for Injections

6.2 Incompatibilities

Not applicable. As specified for the vaccine for which Unisolve is used as the solvent.

6.3 Shelf-life

Shelf-life as packaged for sale (glass vials): 5 years.
Shelf-life as packaged for sale (PET vials): 18 months.
In-use shelf-life: as specified for the vaccine for which Unisolve is used as the solvent.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and composition of immediate packaging

Type II glass vials (Ph. Eur) containing 2, 3, 4, 7, 10, 13, 20, 25, 40, 50, 100 , 200 or 400 ml closed with a halogenated butylrubber stopper and an aluminium crimp cap.

PET vials containing 40 or 100 ml closed with a halogenated butylrubber stopper and an aluminium crimp cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

The disposal information specified for the vaccine for which Unisolve is used as the solvent will apply

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA No. 10996/157/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st September 2006.

10 DATE OF REVISION OF THE TEXT

November 2013