Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Diluvac Forte

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s): Does not contain active ingredients

Adjuvant(s): dl-α-tocopheryl acetate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solvent for parenteral use.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

For reconstitution of lyophilised vaccines for which Diluvac Forte is specified to be used as the solvent.

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 Diluvac Forte 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 Diluvac Forte 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.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known for the solvent, however any recommendations specified for the vaccine for which Diluvac Forte 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.

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

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

4.11 Withdrawal Period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet code: QV07AB
The solvent does not contain active ingredients. The solvent contains an adjuvant, dl-α-tocopheryl acetate. In combination, the adjuvanted solvent and the lyophilised vaccine for which Diluvac Forte is specified to be used with are responsible for the efficacy of the vaccine. The solvent alone does not have immunological properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

DL-α-tocopheryl acetate
Polysorbate 80
Sodium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Simethicone
Water for injections

6.2 Incompatibilities

Do not mix with any other product except the vaccine for which Diluvac Forte is specified to be used with.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale:
4 years in glass
2 years in PET

Shelf-life after dilution or reconstitution according to directions:
In-use shelf-life is that specified for the vaccine for which Diluvac Forte is used as the solvent.

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 packaging

Carton boxes containing one or 10 bottles of glass (type II or I, Ph. Eur.) or polyethylene terephthalate, containing 2, 5, 10, 20, 50, 100 or 200 ml, closed with a halogenobutyl rubber 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

Any solvent which has not been used to reconstitute a lyophilised vaccine should be disposed of in accordance with local requirements. For solvent which has been used to reconstitute a lyophilised vaccine, the disposal instructions for the respective vaccine should be followed.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/208/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th October 2008
Renewal of the last authorisation: 20th September 2013

10 DATE OF REVISION OF THE TEXT