

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphafrol Multivitamin Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances

Vitamin A (Palmitate)	15000	I.U.
Vitamin D ₃ (Cholecalciferol)	7500	I.U.
Vitamin E (alpha-tocopherol acetate)	20	mg
Vitamin B ₁ (Thiamine HCl)	10	mg
Vitamin B ₂ (as sodium phosphate)	5	mg
Vitamin B ₆ (pyridoxine HCl)	3	mg
Vitamin B ₁₂ (Cyanocobalamin)	20	microgram
Nicotinamide	35	mg
d-Panthenol	25	mg

Excipients

Benzyl alcohol (E1519) (Preservative)	9	mg
Phenol solution (85%) (Preservative)	1.8	mg
Butylated hydroxyanisole (E320)	0.1	mg
Butylated hydroxytoluene (E321)	0.1	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

A clear red to dark brown liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves and lambs

4.2 Indications for use, specifying the target species

For the treatment of deficiencies of vitamins A, D₃, E and B in calves and lambs.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Aseptic precautions should be used. Duphafrol Multivitamin administered at intervals as recommended may not adequately cover the requirement of B - vitamins; supplementation with B - vitamin may be necessary.

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

None.

4.6 Adverse reactions (frequency and seriousness)

On rare occasions anaphylactic reactions may occur following the use of this product. In the event of anaphylactic shock, immediate treatment should be given with a soluble glucocorticoid intravenously or adrenaline intramuscularly.

4.7 Use during pregnancy, lactation or lay

No negative effects on the use of Duphafrol Multivitamin during gestation and lactation have been reported.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

By subcutaneous or intramuscular injection.

Dosage

Calves : 7 - 10 ml

Lambs : 3 - 5 ml

The injection may be repeated at intervals of at least 10 days.

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

None.

4.11 Withdrawal Period(s)

Meat: 28 days.

Milk: not permitted for use in lactating animals.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Multivitamins, Combinations.
ATCvet Code: QA11A.

Composite solution containing the Vitamins A1, D3 and E in solubilized form and the major B-vitamins.

Formulated especially for calves and lambs. Adult animals usually require a more simple vitamin preparation.

Aqueous vitamin preparation, so that the animal absorbs the vitamins very quickly. It is therefore ideal for obtaining a quick therapeutic effect.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol solution
Benzyl alcohol (E1519)
Citric acid monohydrate
Disodium edetate
Cremophor ricin oil
Ferric ammonium citrate
Thioglycollic acid
Sodium hydroxide
Butylated hydroxyanisole (E320)
Butylated hydroxytoluene (E321)
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store between 2-8°C.
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

100 ml amber glass Type II vial closed with rubber stopper and aluminium cap.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland Trading as:
Pfizer Animal Health
Ringaskiddy
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/142/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13th February 2009

10 DATE OF REVISION OF THE TEXT

5th August 2011