

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphafral Multivitamin 9 Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:	<u>per ml</u>
Retinol palmitate (Vitamin A)	15,000 IU
Cholecalciferol (Vitamin D ₃)	25 mcg
Alpha tocopheryl acetate (Vitamin E)	20 mg
Thiamine Hydrochloride (Vitamin B ₁)	10 mg
Riboflavin Sodium Phosphate (Vitamin B ₂)	5 mg
Pyridoxine Hydrochloride (Vitamin B ₆)	3 mg
Nicotinamide	35 mg
Dexpanthenol	25 mg
Cyanocobalamin (Vitamin B ₁₂)	25 mcg

Excipient(s):	
Chlorocresol (as preservative)	1 mg
Butylhydroxyanisole (E320)	0.1 mg
Butylhydroxytoluene (E321)	0.1 mg
Disodium Edetate	0.5 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
A clear orange liquid

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

For the prevention and treatment of vitamin deficiencies in horses, particularly during periods of illness, convalescence and general unthriftiness.

4.3 Contraindications

None

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

- i) Special precautions for use in animals

None.

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

Care should be taken to avoid accidental self-injection. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Duphafral Multivitamin 9 can be safely administered to pregnant or lactating horses.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

Administer by intramuscular or subcutaneous injection.

Horses: 20-30ml

The injection may be repeated at intervals of 10-14 days. Normal aseptic precautions should be observed.

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

Not applicable.

4.11 Withdrawal periods

Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation

5. PHARMACOLOGICAL PROPERTIES

ATCvet Code: QA11BA

5.1 Pharmacodynamic properties

Vitamin A is converted to retinol in the eye and is also responsible for the stability of cellular membranes.

Vitamin D₃ plays a major role in the regulation of calcium and phosphate plasma concentrations.

Vitamin E functions as an antioxidant and free radical agent particularly for the unsaturated fatty acids in the phospholipids of cell membranes.

Vitamin B₁ acts as a co-enzyme in the breakdown of glucose and glycogen.

Vitamin B₂ Sodium Phosphate is phosphorylated to form the co-enzymes Riboflavin-5-phosphate and Flavin Adenine Dinucleotide (FAD) which act as hydrogen recipients and donors.

Vitamin B₆ is converted to pyridoxal phosphate which functions as a co-enzyme with the transaminases and decarboxylases in the metabolism of proteins and amino acids.

Nicotinamide is converted to the essential co-enzymes. Nicotinamide Adenine Dinucleotide (NAD) and Nicotinamide Adenine Dinucleotide Phosphate (NADP).

Pantothenol or pantothenic acid is converted to Co-enzyme A which has a key role in the metabolism of carbohydrates and amino acids and in the synthesis of fatty acids, steroids and acetyl co-enzyme A.

Vitamin B₁₂ is required for the synthesis of nucleic acid components, synthesis of red blood cells and the metabolism of propionate.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Butylhydroxyanisole
Butylhydroxytoluene
Citric acid monohydrate – (for pH adjustment)
Sodium hydroxide – (for pH adjustment)
Polysorbate 80
Disodium edentate dihydrate
Propylene glycol
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 16 months
Shelf life after first opening the immediate packaging: 14 days

6.4. Special precautions for storage

Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose use within 14 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

Duphafral Multivitamin 9 is marketed in 100ml amber Type II glass containers, sealed with nitril rubber bungs and aluminium caps.

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

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

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBER


Vm: 42058/4041

9. DATE OF FIRST AUTHORISATION

Date: 08 January 1998

10. DATE OF REVISION OF THE TEXT

Date: February 2014

APPROVED  **28/02/14**