PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (Label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphafral Multivitamin 9 Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

15,000 IU
25 mcg
20 mg
10 mg
5 mg
3 mg
35 mg
25 mg
25 mcg
1 mg
0.1 mg
0.1 mg
0.5 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

SC/IM. Aseptic precautions should be observed.

Dosage: Horses 20 - 30 ml

8. WITHDRAWAL PERIOD

Reviewed: January 2018 (Amended pages)

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.

9. SPECIAL WARNING(S), IF NECESSARY

For uses and warnings: see package leaflet.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

Following withdrawal of the first dose, use within 14 days. Discard unused material.

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

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

POM-VPS

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

5th Floor, 6 St. Andrew Street

London

EC4A 3AE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4041

Reviewed: January 2018 (Amended pages)

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR: Duphafral Multivitamin 9 Solution for Injection

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

Zoetis UK Limited

5th Floor, 6 St. Andrew Street

London

EC4A 3AE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphafral Multivitamin 9 Solution for Injection

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

A sterile injection of vitamins in an aqueous base.

Each ml contains:

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

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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6. ADVERSE REACTIONS

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7. TARGET SPECIES

Horses

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

By intramuscular or subcutaneous injection. Clean the area of the injection site and swab with spirit. Ensure that all injection equipment is thoroughly clean and sterilised before use.

Horses: 20 - 30 ml.

The injection may be repeated at intervals of 10 - 14 days.

9. ADVICE ON CORRECT ADMINISTRATION

Aseptic precautions must be observed when using this product.

10. WITHDRAWAL PERIOD(S)

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.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Following withdrawal of the first dose, use the product within 14 days. Discard unused material. Keep out of the reach and sight of children.

When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Care should be taken to avoid accidental self-injection.

Wash hands after use.

For animal treatment only

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2013

15. OTHER INFORMATION

POM-VPS

To be supplied only on veterinary prescription.

PACKAGE QUANTITIES

Vials of 100 ml.

Vm 42058/4041

Approved: 18/01/2018