# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphafral AD3E Forte

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

| Active Substances | | |
|---|---|---|
| Vitamin A (as propionate) | 500,000 | I.U. |
| Cholecalciferol (Vitamin $D_3$) | 50,000 | I.U. |
| α - tocopherol acetate | 50 | mg |
| **Excipients** | | |
| Butylated Hydroxytoluene | 5.5 | mg |

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for injection. A clear, brownish yellow oily liquid.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle, Sheep and Pigs.

### 4.2 Indications for use, specifying the target species

For the prevention and treatment of Vitamin A and D deficiencies in cattle, sheep and pigs.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

**Special precautions for use in animals**
Aseptic precautions should be observed. Ensure that all injection equipment is thoroughly clean and sterilised before use. Ensure that the site of administration is clean and swabbed with methylated spirit prior to administration.

**Special precautions to be taken by the person administering the product to animals**
None known.

### 4.6 Adverse reactions (frequency and seriousness)

A small local reaction may occur at the site of injection but this should disappear after a short period.

### 4.7 Use during pregnancy, lactation or lay

The product may be administered to pregnant and lactating animals.

**4.8 Interaction with other medicinal products and other forms of interactions**

Not applicable.

**4.9 Amounts to be administered and administration route**

For intramuscular injection.

**DOSAGE**

| | | |
|---|---|---|
| Calves | 0.5 - 1.0 | ml |
| Heifers (12-15 months) | 1 - 2 | ml |
| Cows | 3 - 6 | ml |
| Lambs | 0.25 - 0.5 | ml |
| Sheep | 0.5 - 1 | ml |
| Growing pigs | 0.5 - 1 | ml |
| Sow and boar | 1 - 2 | ml |

For prevention: one injection every 2 - 3 months
For therapeutic purposes:injections may be given at shorter intervals. Appropriate timing of treatments will depend on a variety of factors including age, diet, management factors, etc..

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

If overdosed, Vitamin D3 can cause calcification of blood vessels. The risk of development of calcification following overdose of vitamin D3 will be influenced by a variety of other factors including age and dietary Ca/P ratio.

**4.11 Withdrawal period(s)**

Milk from treated animals intended for human consumption may only be taken after 5 days from the date of the last treatment.

Animals intended for human consumption may only be slaughtered after 28 days from the date of last treatment.

**5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Duphafral ADE Forte is used in the prevention and treatment of Vitamin A and D deficiencies in cattle, sheep and pigs.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Butylated Hydroxytoluene
Polysorbate 80
Triacetin

**6.2 Major incompatibilities**

None known.

**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**

Do not store above 25°C.

Protect from light.
Do not freeze.
In very low temperatures the liquid may take on a heterogeneous form.
It should be gradually warmed to restore its normal consistency.

**6.5 Nature and composition of immediate packaging**

Amber Type II glass bottle of 50 ml closed with bromobutyl rubber stopper.

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

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**

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA10387/022/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 01 October 1996
Date of last renewal: 30 September 2006

**10 DATE OF REVISION OF THE TEXT**

March 2016