Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphafral D_3 1000 Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance	
Colecalciferol	1,000,000 I.U.
Excipients	
Benzyl alcohol	9 mg
Propylene glycol	100 mg

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Duphafral D_3 1000 is indicated for the prevention of milk fever in cows.

4.3 Contraindications

Do not use in animals with known hypersensitivity to injectable vitamin solutions.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Aseptic precautions must be observed when using the product. Ensure that site of injection is clean and swabbed with iodine or spirit prior to administration.
Duphafral D3 1000 is a useful adjunct in the prevention of Milk Fever in cattle. However management and feeding practices must also be adjusted in order to achieve optimum results.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Calcification of blood vessels has been observed following repeated high doses of Vitamin D_3.

In the event of an allergic or anaphylactic reaction, immediate treatment should be given with a soluble glucocorticoid intravenously (e.g. dexamethasone sodium phosphate) or epinephrine (adrenaline) intramuscularly.

The product contains a polyethoxylated castor oil as non-ionic surfactant and can provide severe anaphylactic reactions associated with histamine release.

4.7 Use during pregnancy, lactation or lay

No negative effects of the use of Duphafral D_3 1000 during gestation and lactation are reported.

4.8 Interaction with other medicinal products and other forms of interaction

No concomitant treatment may be given at the same injection site.

4.9 Amounts to be administered and administration route

Administration is by strict intramuscular injection, using a sterile needle and syringe.
Clean and disinfect the injection site.
The contents of one vial (10 ml) should be injected between 8 and 2 days before the estimated calving date. In case the animal has not yet calved before or at the estimated calving date a second dose (10 ml) can be injected not earlier than 8 days after the first injection.

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

Calcification of blood vessels has been observed, following repeated high doses of vitamin D_3.
Symptoms of vitamin D intoxication include anorexia, weight loss, intestinal stasis, dyspnoea and polyuria.

4.11 Withdrawal Period(s)

Meat and offal: 28 days
Milk: zero hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Vitamin D and analogues.

ATC vet code: QA11CC05

Duphafral D_3 1000 regulates the metabolism of calcium in the cow, during the critical period of 10 days preceding calving.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Propylene glycol
Arachis Oil
Hydrochloric Acid
Citric Acid
Sodium Phosphate Dodecahyrate
Polyoxyl 35 Castor Oil
Water for Injection

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

From the literature it is known that most vitamins are very sensitive to oxidising substances and/or pH-changes.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

For single use only.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

10 ml amber coloured type I glass vials with a red butyl stopper and natural coloured aluminium capsule, containing a pale yellow oily solution.

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

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 Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/031/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2010

10 DATE OF REVISION OF THE TEXT

August 2013