Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphafral Extravite.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s)	
Thiamine Hydrochloride	35.0 mg/ml
Riboflavin Sodium Phosphate	0.5 mg/ml
Pyridoxine Hydrochloride	7.0 mg/ml
Nicotinamide	23.0 mg/ml
Ascorbic Acid	70.0 mg/ml
Excipient	
Chlorocresol	1.0 mg/ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection. A pale yellow to brown aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep, Pigs.

4.2 Indications for use, specifying the target species

For the treatment of cerebrocortical necrosis in cattle and sheep, and for the treatment of Vitamin B deficiencies in cattle, sheep and pigs.

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substance.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None known.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Duphafral Extravite may occasionally cause local reaction at the site of injection. This should resolve naturally within a short period of time.

4.7 Use during pregnancy, lactation or lay

Duphafral Extravite can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administer by subcutaneous or intramuscular injection. The dose should be repeated daily as required. Avoid the introduction of contamination during use.

Cattle	20 - 30 ml
Calves	5 - 10 ml
Sheep and Pigs	5 - 10 ml

If dose volume exceeds 20 ml, it should be divided and injected into two sites.

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

Not applicable.

4.11 Withdrawal Period(s)

Edible tissues and milk: zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Thiamine Hydrochloride (Vitamin B1) acts as a co-enzyme in the breakdown of glucose and glycogen.
Riboflavin Sodium Phosphate (Vitamin B2) is phosphorylated to form the co-enzymes Riboflavin-5-phosphate and Flavin Adenine Dinucleotide (FAD) which act as hydrogen recipients and donors.
Pyridoxine Hydrochloride (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 into the essential co-enzymes Nicotinamide Adenine Dinucleotide (NAD) and Nicotinamide Adenine Dinucleotide Phosphate (NADP).
Vitamin C (Ascorbic Acid) is involved in the conversion of folic acid to tetrahydrofolic acid and the conversion of proline to hydroxyproline, which is essential to the formation of collagen.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol

6.2 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

Store below 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

The product is marketed in 50 ml and 100 ml amber Type II glass vials, sealed with bromobutyl bungs and aluminium caps.

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

Zoetis Limited Ireland
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/032/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2006

10 DATE OF REVISION OF THE TEXT

August 2013