

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

DUPHALYTE Solution for injection

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Active substances:**

	Composition per ml
<b>VITAMINS</b>	
Thiamine Hydrochloride	0.167mg
Riboflavin (as Riboflavin sodium phosphate)	0.084mg
Pyridoxine Hydrochloride	0.20mg
Nicotinamide	2.25mg
Dexpanthenol	0.10mg
<b>ELECTROLYTES</b>	
Calcium chloride hexahydrate	0.23mg
Magnesium Sulphate heptahydrate	0.29mg
Potassium chloride	0.20mg

#### **Excipients:**

Methyl (preservative)	hydroxybenzoate	1.80mg
Propyl (preservative)	hydroxybenzoate	0.20mg
Phenol (preservative)		0.10mg
Disodium edetate (preservative)	dehydrate	0.15mg

For the full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Solution for injection.  
A clear yellow solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Horses, dogs, cats, swine and cattle.

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

As supportive maintenance therapy in conditions of fluid loss in horses, cattle, pigs, dogs and cats.

#### **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

Aseptic precautions must be observed when using the product.

Administer very slowly when the injection is given intravenously. Too rapid injection may cause nausea and distress. If this occurs, discontinue until animal returns to normal and continue at slower rate.

The product should be at normal body temperature when administered.

When administered to calves or young pigs by the subcutaneous route, pain may occur at the injection site. This is usually of a transient nature. Care should be taken to reduce such reactions to a minimum. For welfare reasons it is essential that adequate instructions are given to operators.

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 known

#### **4.7 Use during pregnancy, lactation or lay**

The product may be used in 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

Duphalyte should be administered:

*To horses:*

By slow intravenous injection only.

*To cattle and pigs:*

By slow intravenous injection only.

*To calves and young pigs under three years of age:*

Following initial intravenous administration, follow-up therapy, if required, may be administered by the subcutaneous route. In such cases, the dose should be divided and administered at two or more sites.

*To cats and dogs:*

By slow intravenous injection only.

##### **Recommended doses:**

*Horses, cattle, sows and boars:*

Up to 100ml per 50kg bodyweight.

*Foals, calves and younger pigs:*

Up to 30ml per 5kg bodyweight.

*Dogs and cats:*

Up to 50ml per 5kg bodyweight.

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

Excessive or continuous usage should be avoided because of interactions with dietary vitamins or minerals.

#### 4.11 Withdrawal periods

Cattle, horses, swine (meat): Zero days

Cattle (milk): Zero hours.

### 5. PHARMACOLOGICAL PROPERTIES

**Pharmacotherapeutic group:** Vitamins, Multivitamins combinations, Multivitamins with minerals

**ATCvet Code:** QA11AA03

The product consists of a combination of B-complex vitamins, electrolytes, amino acids and dextrose for use as supportive maintenance therapy in conditions of fluid loss.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Methyl hydroxybenzoate (preservative)  
Propyl hydroxybenzoate (preservative)  
Phenol (preservative)  
Disodium edetate dehydrate (preservative)  
Anhydrous Glucose Anhydrous  
L-arginine hydrochloride  
L-cysteine hydrochloride monohydrate  
Monosodium glutamate monohydrate  
Cyanocobalamin  
L-histidine hydrochloride monohydrate  
L-isoleucine  
L-leucine  
L-lysine hydrochloride  
L-methionine  
DL-phenylalanine  
L-threonine  
DL-tryptophane  
DL-valine  
Sodium acetate trihydrate  
Citric acid monohydrate (for pH adjustment)  
Water for injections

### **6.2 Major incompatibilities**

As some vitamins are sensitive to oxidising substances and/or pH changes, Duphalyte should not be mixed for administration with any other product. For this reason it is recommended not to mix Duphalyte with other medicinal products.

### **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.  
Do not freeze.  
Protect from light.  
Following withdrawal of the first dose, use the product within 28 days.  
Discard unused material.

### **6.5 Nature and composition of immediate packaging**

500ml opaque polypropylene bottles, with chlorobutyl rubber stoppers with aluminium overseals.

**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  
1<sup>st</sup> Floor, Birchwood Building  
Springfield Drive  
Leatherhead  
Surrey  
KT22 7LP

**8. MARKETING AUTHORISATION NUMBER**

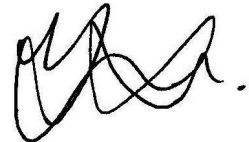
Vm 42058/4042

**9. DATE OF FIRST AUTHORISATION**

25 July 2000

**10. DATE OF REVISION OF THE TEXT**

August 2020



Approved: 26 August 2020