1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphalyte Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances	Per ml	
Calcium chloride hexahydrate	0.23	mg
Magnesium sulphate heptahydrate	0.29	mg
Potassium chloride	0.20	mg
Thiamine hydrochloride	0.10	mg
Riboflavin (as sodium phosphate)	0.04	mg
Pyridoxine hydrochloride	0.10	mg
Cyanocobalamin	0.05	µg
Nicotinamide	1.50	mg
Dexpanthenol	0.05	mg

Amino Acids and Nutritional Agents		
Glucose anhydrous	45.46	mg
Arginine hydrochloride	0.025	mg
Cysteine hydrochloride monohydrate	0.01	mg
Monosodium glutamate monohydrate	0.04	mg
Histidine hydrochloride monohydrate	0.01	mg
Isoleucine	0.01	mg
Leucine	0.04	mg
Lysine hydrochloride	0.03	mg
Methionine	0.01	mg
dl-phenylalanine	0.03	mg
Threonine	0.02	mg
dl-Tryptophane	0.01	mg
dl-Valine	0.05	mg

Excipients		
Methyl parahydroxybenzoate (E218)	1.80	mg
Propyl parahydroxybenzoate (E216)	0.20	mg

Phenol (85 per cent solution)	0.10	mg

For a 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

Cattle, horses, swine, cats and dogs.

4.2 Indications for use, specifying the target species

To be used as a supportive maintenance therapy in conditions of fluid loss, electrolyte imbalance and hypoproteinaemia in horses, cattle, pigs, dogs and cats.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

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.
When administered intravenously, an intravenous set with filter should be used and the product should be administered very slowly. The infusion rate should not exceed 2 ml/kg/hour.

Special precautions to be taken by the person administering the product to animals
Persons with known sensitivity to any ingredient of the product should avoid contact with the product. Should anyone accidentally be injected with the product during administration, a doctor should be consulted immediately and be informed of the nature of the product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

No negative effects on the use of Duphalyte during gestation and/or lactation have been reported.

4.8 Interaction with other medicinal products and other forms of interaction

No clinical interactions have been reported.

4.9 Amounts to be administered and administration route

Route of administration
Horses by slow intravenous injection only.
Cattle and pigs by slow intravenous, intraperitoneal or subcutaneous injection.
Dogs and cats by slow intravenous or subcutaneous injection.

Dosage
Horses, cattle, swine 2 ml/kg body weight
Foals, calves, piglets 6 ml/kg body weight
Dogs and cats 10 ml/kg body weight

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

Not applicable.

4.11 Withdrawal period(s)

Nil. Animals may be slaughtered for human consumption following treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Duphalyte is a supportive maintenance therapy in conditions of fluid loss, electrolyte imbalance and hypoproteinaemia in horses, cattle, swine, dogs and cats.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Phenol (85 per cent solution)
Disodium Edetate
Sodium Acetate
Citric Acid Monohydrate

Water for Injections

6.2 Incompatibilities

Vitamins are sensitive to oxidising substances and pH changes, therefore do not mix the veterinary medicinal product with any other product.

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. Discard any unused material.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is marketed in 500 ml polypropylene bottles which are closed with rubber stoppers.

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

Any unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/023/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1991
Date of last renewal: 30th September 2006

10 DATE OF REVISION OF THE TEXT

August 2017