

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
VITAMINS	
Thiamine Hydrochloride	0.167mg
Riboflavin (as Riboflavin sodium phosphate)	0.084mg
Pyridoxine Hydrochloride	0.20mg
Nicotinamide	2.25mg
Dexpanthenol	0.10mg
ELECTROLYTES	
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
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

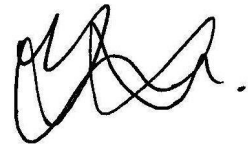
Vm 42058/4042

9. DATE OF FIRST AUTHORISATION

25 July 2000

10. DATE OF REVISION OF THE TEXT

August 2020

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

Approved: 26 August 2020