PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphalyte® Solution for Injection

Vitamin B-complex – Electrolytes – Amino acids - Dextrose

2. STATEMENT OF ACTIVE SUBSTANCES

COMPOSITION per ml:

VITAMINS

Thiamine Hydrochloride	0.167 mg
Riboflavin (as Riboflavin sodium phosphate)	0.084 mg
Pyridoxine Hydrochloride	0.20 mg
Nicotinamide	2.25 mg
Dexpanthenol	0.10 mg

ELECTROLYTES

Calcium chloride hexahydrate	
Magnesium sulphate heptahydrate	0.23 mg
Potassium chloride	0.29 mg
	0.20 mg

AMINO ACIDS

L-arginine hydrochloride	
L-cysteine hydrochloride monohydrate	0.025 mg
Monosodium glutamate monohydrate	0.01 mg
L-hystidine hydrochloride monohydrate	0.04 mg
L-isoleucine	0.01 mg
L-leucine	0.01 mg
L-lysine hydrochloride	0.04 mg
L-methionine	0.03 mg

DL-phenylalanine	0.01 mg
L-threonine	0.03 mg
DL-tryptophan	0.02 mg
DL-valine	0.01 mg
	0.05 mg

DEXTROSE

Anhydrous dextrose	
	45.46 mg

EXCIPIENTS

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

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs and cats.

6. INDICATIONS

A supportive fluid therapy for animals.

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

A sterile injectable solution to be used for animal treatment only.

7. METHOD AND ROUTES OF ADMINISTRATION

Horses, cattle, pigs, dogs and cats: by slow intravenous injection only.

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.

Aseptic precautions should be observed when using this solution.

Dosage:

Horses, cattle, sows and boars:	up to 100 ml per 50 kg bodyweight
Foals, calves and younger pigs:	up to 30 ml per 5 kg bodyweight
Dogs and cats:	up to 50 ml per 5 kg bodyweight

8. WITHDRAWAL PERIOD

Cattle, horses, swine (meat): Zero days.
Cattle (milk): Zero hours.

9. SPECIAL WARNINGS, IF NECESSARY

Too rapid injection may cause nausea and distress. If this occurs, discontinue until animal returns to normal and continue at a slower rate.

Duphalyte should be at normal body temperature when administered.

Sterile equipment and aseptic handling required.

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

User Warnings:

Care should be taken to avoid accidental self-injection. Wash hands after use.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze. Protect from light.

Do not mix with other products. Keep container in outer carton.

Following withdrawal of the first dose, use the product within 28 days.

Once broached use by:

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

1st Floor, Birchwood Building

Springfield Drive

Leatherhead

Surrey

KT22 7LP

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Ctra. Camprodon s/n "la Riba"
17813 Vall de Bianya
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4042

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Outer label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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Vitamin B-complex – Electrolytes – Amino acids - Dextrose

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3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 x 500 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs and cats.

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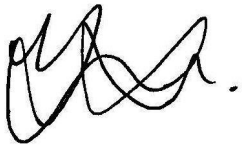

Approved: 26 August 2020