

## ΠΑΡΑΡΤΗΜΑ 1: ΠΕΡΙΛΗΨΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

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### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEATOX, solution for injection for cattle, horses, swine, dogs and cats.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

#### Active substances:

cyanocobalamin (Vit. B <sub>12</sub> ).....	0.005 mg
fructose.....	50 mg
liquid sorbitol, crystallizable.....	50 mg
sodium chloride.....	6 mg
sodium lactate.....	3.048 mg
potassium chloride.....	0.4 mg
calcium chloride.....	0.2 mg
magnesium chloride.....	0.2 mg
L-arginine.....	1.98 mg
equivalent to L-arginine hydrochloride.....	2.39 mg
L-ornithine.....	0.94 mg
equivalent to L-ornithine hydrochloride.....	1.2 mg
L-citrulline.....	1.2 mg

#### Excipients:

sodium methyl parahydroxybenzoate (E219) .....	1.06 mg
sodium propyl parahydroxybenzoate (E217) .....	0.14 mg
other excipients and water for injections q.s. to.....	1 ml

For a full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Solution for injection.

### 4. CLINICAL PARTICULARS

#### 4.1. Target species

Cattle, horses, swine, dogs and cats.

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

States of exogenous or endogenous intoxication following diseases and/or special rearing conditions, diarrhoea (infectious or not), transport stress, pregnancy, hyperproteic diet, excess of urea, parturient paresis, acetonemia; dehydration, acidosis and states of debilitation.

**4.3. Contraindications**

Cardiac insufficiency, conditions associated with hyperkalemia. Use with caution in cases of congestive heart failure, severe renal insufficiency and in clinical states associated with oedema and fluid-electrolyte retention.

**4.4. Special warnings for each target species**

None.

**4.5. Special precautions for use**

**Special precautions for use in animals**

Administration into a large vein is recommended, with a controlled rate of perfusion. This is used for just one uninterrupted administration and any residual product cannot be used.

Apply normal aseptic precautions.

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

None.

**4.6. Adverse reactions (frequency and severity)**

Intravenous administration of this solution can cause, owing to its sodium content, edema in animals with salt retention.

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

It can be used during pregnancy and lactation.

**4.8. Interaction with other medicinal products and other forms of interaction**

None known.

**4.9. Amounts to be administered and administration route**

NEATOX must be administered by the subcutaneous, intraperitoneal or intravenous routes.

<b>Adult horses and cattle:</b>	250-500 ml/animal.
<b>Calves, foals and adult pigs:</b>	150-250 ml/animal.
<b>Dogs and cats:</b>	20-50 ml/animal.

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

No symptoms due to overdose are known.

#### **4.11. Withdrawal periods**

Meats: 0 days.

Milk: 0 hours.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Solutions which influence the electrolytic balance. Electrolytes associated with carbohydrates.

ATC Vet Code: QB05BB02

#### **5.1. Pharmacodynamic properties**

NEATOX is a solution for injection composed of an association of vitamin B<sub>12</sub> (cyanocobalamin), sugars (fructose and sorbitol), electrolytes (sodium, potassium, calcium and magnesium) and amino acids (arginine, ornithine, citrulline).

Vitamin B<sub>12</sub>, owing to its direct action on synthesis of proteins and nucleoproteins, favours a net improvement in changes to protein metabolism and also, owing to its activity on methionine synthesis, produces an indirect antisteatotic action, contributing to protect the liver from degenerative processes.

Sorbitol and fructose are two carbohydrates, the fundamental characteristic of which is that of being immediately deposited in the liver, partly in the form of glycogen, partly in the form of glucose; this supplies the hepatic cell with an immediately useable source of energy, thus interrupting alternative metabolic processes (utilisation of amino acids and fats), the cause of further complications (acetonemia). Sorbitol, moreover, as a supplementary activity, possesses a bland diuretic action which is extremely useful in restoring renal function, often compromised following toxic disorders of the blood.

The electrolytes (sodium, potassium, calcium, magnesium) contained according to the proportions in Ringers lactate solution, enable a fundamental salt reintegration in debilitated and dehydrated animals.

Arginine, ornithine and citrulline, permit a notable increase in the transformation of ammonia into urea by treated animals and thus reduce a cause of toxicosis which is anything but infrequent, particularly in intensively reared animals, often subjected to hyperproteic diets.

NEATOX is a preparation with a detoxifying and rehydrating action, in addition to being a hepatoprotective, energising and vitaminic agent.

## **5.2. Pharmacokinetic particulars**

Vitamin B<sub>12</sub> binds to specific proteins and distributes rapidly to all tissues, particularly the liver, where it is stored. Any excess is excreted principally by the renal route.

Sorbitol is oxidised to fructose, which is converted in the liver to glucose-6-phosphate; the latter is metabolised to polymers and subsequently to glycogen. Excess fructose and sorbitol are excreted, principally by the renal route.

Sodium, potassium, calcium and magnesium salts release their respective electrolytes into the bloodstream, distributing to the various systems of the organism, intervening in numerous metabolic processes. Sodium, potassium and magnesium are excreted principally with the urine, while calcium is also eliminated with the feces.

Arginine, ornithine and citrulline undergo processes of transformation and degradation in the liver, common to all the amino acids; the nitrogen which is produced is partly reused and partly excreted, principally by the renal route.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

Sodium methyl parahydroxybenzoate (E219)

Sodium propyl parahydroxybenzoate (E217)

Citric acid, anhydrous (E330)

Water for injections

### **6.2. Incompatibilities**

Avoid mixing with drugs based on bicarbonates, phosphates, sulphates and tetracyclines.

### **6.3. Shelf-life**

Shelf-life for the veterinary medicinal product as packaged for sale: 2 years.

Shelf-life after first opening the immediate packaging: 28 days.

In perfusion administrations, in which the drip-tube is inserted in the bottle, the medicinal product must be used immediately after first opening and any residual product must be discarded and not stored.

### **6.4. Special precautions for storage**

Store protected from light and sources of heat.

**6.5. Nature and composition of the immediate packaging**

250 ml type I glass bottle, with an elastomer closure and aluminium collar in a cardboard box.

**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**

FATRO S.p.A. - Via Emilia, 285 - Ozzano Emilia (Bologna), Italy.

**8. MARKETING AUTHORISATION NUMBER**

10456

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

7/5/1986,31/5/2012

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

31/5/2012