

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Nutrancel 400 Electrolyte Solution for Infusion

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active Substance

Each 1 litre contains:

Anhydrous Glucose	200.00	g
<u>or</u>		
Dextrose Monohydrate	218.00	g
Magnesium Chloride	3.66	g
Calcium Chloride	2.21	g
Zinc Acetate	17.56	mg
Manganese Chloride Tetrahydrate	2.0	mg

Yielding the following concentration of electrolytes per 500ml:

Calcium	7.5	mmol
Magnesium	9.0	mmol
Chloride	33.0	mmol
Zinc	40.0	µmol
Manganese	5.0	µmol
Acetate	80.0	µmol

For excipients see 6.1.

#### 3 PHARMACEUTICAL FORM

Solution for Infusion

A sterile, non-pyrogenic, clear, colourless solution for infusion.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Nutrancel 400 Electrolyte Intravenous Solution is indicated as an energy source and electrolyte supplement in parenteral nutrition. For intravenous administration.

##### 4.2 Posology and method of administration

The total daily dosage is dependent upon the age, weight, clinical state and degree of deficiency of the patient and must be determined on an individual basis.

### 4.3 Contraindications

The product is contraindicated in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis) and

1. In patients with severe impairment of renal function or in patients whose serum levels of magnesium calcium, zinc or manganese are considered abnormally high.
2. The use of a solution which is cloudy, contains sediment or is in any way unusual.

Manganese is excreted by the bile and should not be administered to patients with biliary obstruction.

### 4.4 Special warnings and special precautions for use

These solutions are hypertonic and may cause venous irritation if administered by peripheral vein, therefore prolonged peripheral intravenous infusion should be avoided. It is recommended that administration should be through a silicone rubber central venous catheter preferably directly into the left subclavian vein and placed by an experienced operator.

Administration should be carried out only under specialist surveillance. This fluid should only be administered with great care in patients with diabetes mellitus, renal insufficiency or a history of renal stone formation. The need for electrolyte control should be kept in mind.

The rate of administration of this solution should be slow to avoid cardiotoxicity.

### 4.5 Interaction with other medicinal products and other forms of interaction

Calcium salts enhance the effects of digitalis on the heart and may precipitate digitalis intoxication.

### 4.6 Pregnancy and lactation

The safety of the use of parental nutrition mixtures in pregnant women has not been established.

### 4.7 Effects on ability to drive and use machines

Not applicable

### 4.8 Undesirable effects

Not applicable

### 4.9 Overdose

Overdosage would be expected to result in circulatory embarrassment or pulmonary oedema, in which case the infusion should be stopped and specific treatment given.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Not applicable

### 5.2 Pharmacokinetic properties

Not applicable

### **5.3 Preclinical safety data**

Not applicable

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Water for Injections.

### **6.2 Incompatibilities**

Do not administer simultaneously with, before or after an administration of blood through the same infusion equipment because of the possibility of pseudoagglutination.

### **6.3 Shelf Life**

Unopened: 2 years.

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

Do not store above 25°C.

### **6.5 Nature and contents of container**

The product is a clear, colourless solution in a plastic Viaflex® container. The plastic is plasticised PVC (poly (vinyl chloride)).

The containers are sealed in a plastic overpouch. The solutions are supplied in 500ml, 2000ml and 3000ml fill volumes.

Not all pack sizes may be marketed.

### **6.6 Instructions for use and handling**

Do not use unless solution is clear and the container is undamaged.

For use on one occasion only. Do not store partly used containers.  
Discard all equipment after use.

It is recommended that all intravenous apparatus be replaced at least every 24 hours.

## **7 MARKETING AUTHORISATION HOLDER**

Baxter Healthcare Ltd  
Caxton Way  
Thetford  
Norfolk IP24 3SE  
UK

## **8 MARKETING AUTHORISATION NUMBER**

PA 167/94/1

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

Date of first authorisation: 6<sup>th</sup> December 1993

Date of last renewal: 6<sup>th</sup> December 2003

**10 DATE OF REVISION OF THE TEXT**

July 2004