Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Intrafusin 22 Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000 ml bottle of Intrafusin 22 contains:

Isoleucine Ph. Eur.	4.2	g
Leucine Ph. Eur.	5.7	g
L-Lysine-L-Glutamate.2H_2O	15.15	g
(equivalent to Lysine and Glutamic acid)	6.75 6.75	g g
Methionine Ph. Eur.	5.4	g
Phenylalanine Ph. Eur.	4.1	g
Threonine Ph. Eur.	5.4	g
Tryptophan Ph. Eur.	2.1	g
Valine Ph. Eur.	4.7	g
Arginine Ph. Eur.	14.0	g
Histidine Ph. Eur.	3.5	g
N-Acetyl-L-Cysteine Ph. Eur.	0.7	g
Glycine Ph. Eur.	15.6	g
Alanine Ph. Eur.	26.0	g
Glutamic Acid Ph. Eur.	15.3	g
Proline Ph. Eur.	14.1	g
Serine Ph. Eur.	14.1	g
N-Acetyl-L-tyrosine Ph. Eur.	2.25	g
Total amino acids	**152.3**	**g**

Product properties

Energy content/litre	600 kcal
Nitrogen content/litre	22.8 g
Osmolality	1440 mosmol/kg water
pH	5.2
Titratable acidity (pH 7.4) approx.	45.5 mmol/l
Acetate	Nil

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Clear, colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

To be used as part of an intravenous parenteral nutrition regimen, which is indicated whenever oral feeding is impossible or inadequate.

4.2 Posology and method of administration

For intravenous use only.

Dosage and administration
The amount of Intrafusin 22 to be administered daily is calculated according to individual patients' requirement of nitrogen, fluid etc.

Recommended dosage for adults (including the elderly)
Adults should receive 1.0-2.0 g amino acids/kg body weight/day, which equates to approximately 6.5-13 ml/kg body weight/day of Intrafusin 22. In a 70 kg patient, this would result in an infusion volume of 450-900 ml/day.

Pregnant and post-operative patients should receive 1.6-2.0 g amino acids/kg body weight/day.

An infusion rate of 0.9-1.3 ml/kg body weight/hour is recommended, which in a 70 kg patient corresponds to 63-91 ml/hour. The infusion rate should not exceed 1.3 ml/kg body weight/hour. One litre of solution should be given over not less than 11-12 hours.

Recommended dosage for children
The product is not recommended for use in children.

4.3 Contraindications

Intrafusin 22 is contraindicated in patients suffering from severe shock, hyperkalaemia, severe disturbances of liver or kidney function and disturbance of amino acid metabolism.

4.4 Special warnings and precautions for use

The effects of Intrafusin 22 should be carefully controlled when given to patients who tend toward elevated serum potassium or urea levels. Too rapid an infusion may result in renal losses, and nausea in sensitive patients.

A pre-existing deficiency of vitamins and, in particular, folic acid and vitamin B_{12} may become clinically evident during intravenous nutrition with amino acids. Regular checks of the patients' vitamin B_{12} status and folate demand are therefore recommended. Prophylactic administration of adequate vitamins should be given if required.

The solution of Intrafusin 22 should be clear at all times before infusion. Discard the solution if a precipitate or severe discolouration occurs.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

None known.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Not expected.

4.9 Overdose

In the event of fluid or solute overload during parenteral therapy, re-evaluate the patient's condition and institute appropriate corrective treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The pharmacological actions (over and above the normal physiological function) of the amino acids present in the Intrafusin 22 formulation are well documented. The concentration and rate of infusion is designed to maintain normal physiological levels of amino acids only. No pharmacological effects are therefore expected.

5.2 Pharmacokinetic properties

The distribution and elimination of amino acids is dependant on the physiological status of the patient. Whilst normal limits for each can be defined, the rates of elimination may be very variable.

This formulation of amino acids is intended to normalise circulating amino acid levels and the composition and rate of administration are designed to achieve this.

The N-acetyl amino acids are rapidly deacetylated to give the respective free amino acids.

5.3 Preclinical safety data

No further preclinical safety data are available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections.

6.2 Incompatibilities

Additions to the amino acid solution or giving set should be avoided unless compatibility is known.

6.3 Shelf life

3 years.

Once opened use immediately and discard any remaining contents.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate.

6.5 Nature and contents of container

Glass bottle (Type II) Ph. Eur. with butyl rubber or ethylene propylene terpolymer stopper, containing 500 ml or 1000 ml of solution.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only. Discard any remaining contents.

The manufacturer can be consulted for further stability information on parental nutrition regimens containing Intrafusin 22.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 566/7/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 16 August 2009

10 DATE OF REVISION OF THE TEXT

September 2012