
SUCLAMIN

Iron Minerals, Amino Acid & B-Complex Syrup

Summary of Product Characteristics

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1 NAME OF THE MEDICINAL PRODUCT

Iron Minerals Amino Acid & B-Complex Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains:

Ferric Ammonium Citrate	BP	150 mg
Eq. To Elemental Iron		32 mg
Protein Hydrolysate 20 %	BP	1 gm
Eq. to Total Nitrogen		30 mg
Folic Acid	BP	1 mg
L-Lysine HCl	USP	50 mg
Pyridoxine HCl	BP	1.5 mg
Niacinamide	BP	45 mg
Cyanocobalamin	BP	7.5 mcg
D- Panthenol	BP	5 mg
Zinc (As sulphate)	BP	44 mg
Eq. To Elemental Zinc		10 mg
in as Flavoured Syrup Base.		

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORMS

Oral Syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indication.

As a therapeutic supplement for the prevention of Iron, Minerals, Amino Acids vitamin deficiency in conditions such as galactosaemia, disaccharide intolerance, phenylketonuria and other disorders of carbohydrate or amino acid metabolism, as well as in patients who are on restricted, specialised or synthetic diets.

4.2 Posology and method of administration.

For Adults & Children: 5 ml three times a day, by oral administration.

4.3 Contraindications

Hypersensitivity to the product.

4.4 Special warnings and precaution for use.

None stated.

4.5 Interaction with other medicinal product and other forms of interaction.

Pyridoxine may increase the peripheral metabolism of levodopa reducing therapeutic efficacy in patients with Parkinson's disease.

4.6 Pregnancy and Lactation.

The recommended dose should not be exceeded without medical advice.

4.7 Effect on the ability to drive and use machine.

None.

4.8 Undesirable effect.

Not stated.

4.9 Overdose.

Large overdoses of water-soluble vitamins are readily excreted in the urine. No emergency procedure or antidote is applicable and any symptoms are rapidly reduced upon withdrawal of the preparation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

Iron, Minerals Amino Acids and Multivitamin preparation.

5.2 Pharmacokinetic properties.

In normal circumstances the active constituents are obtained by the same route of administration

5.3 Preclinical safety data.

No relevant pre-clinical data has been generated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sugar	BP
Sorbitol (70%) solution	BP

Glycerin	BP
Sodium Methyl Paraben	BP
Sodium Propyl Paraben	BP
Liquid Glycose	BP
Sodium Benzoate	BP
Disodium EDTA	BP
Sodium Citrate	BP
Citric Acid Monohydrate	BP
Sodium Saccharine	BP
Sodium Hydroxide	BP
Colour Caramel	In house
Xanthan Gum	BP
Mixed Fruit Flavour	In house

6.2 Incompatibilities

unknown

6.3 Shelf-life

24 months

6.4 Special precautions for storage

Store at temperature not exceeding 30°C. Protect from light.

6.5 Nature and composition of immediate packaging

Brown colour viscous liquid with a characteristic flavor filled in 200mL PET bottle.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

None.

7 MARKETING AUTHORISATION HOLDER**8 MARKETING AUTHORISATION NUMBER(S)****9 AUTHORISATION/RENEWAL OF THE AUTHORISATION****10 DATE OF REVISION OF THE TEXT**

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