SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

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1. **NAME OF THE MEDICINAL PRODUCT**

Intaplex Tablets

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each Tablet contains: Nicotinamide BP 15mg; Riboflavin BP 1mg; Thiamine HCl BP 1 mg.

3. **PHARMACEUTICAL FORM**

Tablet

4. **CLINICAL PARTICULARS**

4.1. **Therapeutic indications**

As a therapeutic supplement for the prevention of 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, specialized or synthetic diets

4.2. **Posology and method of administration**

Route of administration: Oral

Method of administration:

For Adults, Children and the Elderly: One tablet three times a day, by oral administration. Or as directed by the doctor

4.3. **Contraindications**

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1

4.4. **Special warnings and precautions for use**

None stated.

4.5. **Interaction with other medicinal products 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. **Effects on ability to drive and use machines**

No or negligible influence on the ability to drive and use machines

4.8. **Undesirable effects**

Tabulated list of adverse reactions

System Organ Class	Frequency	Adverse reactions
Immune system disorders	Not known (cannot be estimated from the available data)	Anaphylactic reaction

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

Multivitamin preparation.

Pharmacotherapeutic group: Vitamin B-complex, other combinations.

5.2. Pharmacokinetic properties

In normal circumstances the active constituents are obtained by the same route of administration (oral) from food.

5.3. Preclinical safety data

No relevant pre-clinical data has been generated..

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Starch

Microcrystalline Cellulose PH 101

Lactose

Sodium Benzoate

Potassium Sorbate

Tartrazine Yellow FD & Yellow 5 colour (E102)

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2years.

6.4. Special precautions for storage

Store below 30°C away from light and moisture

6.5. Nature and contents of container

Aluminium foil

Length: 96±1mm

Thickness: 0.3mm

Weight of the material: 0.735 gsm

PVC

Type: Rigid PVC film

Length: 96±1 mm

Thickness: 250 microns ±7%

Colour: Clear

Unit carton

Length: 103±2mm

Width: 65±2mm

Height: 13 ±2mm

Weight of the material: 220 gsm

Caliper: 400 microns

Leaflet

Length148± 2mm

6.6. Width: 105±2mm

Weight of the material: 50gsm

Caliper: 55 microns

6.7. **Special precautions for disposal and other handling**

No special requirements.

7. REGISTRANT

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8. MANUFACTURER

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