



UGOLAB PRODUCTIONS (NIG.) LTD.

MANUFACTURERS OF PHARMACEUTICAL PRODUCTS AND GENERAL MERCHANTS

Head office: 31A Burma Road, Sabon Gari, Kano.

Factory: 157/159, Club Road, Bompai Ind. Layout, Kano.

Tel: +234 (80) 23094219

Website: www.ugolab.com

Email: ugolabpharm@yahoo.com

SUMMARY OF PRODUCT CHARACTERISTICS LAB B PLEX

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SUMMARY OF PRODUCT CHARACTERISTICS LAB B PLEX

1. Name of the medicinal product

LAB B PLEX

2. Qualitative and quantitative composition

Each 5ml contains

THIAMINE HCL (B1) 5MG

RIBOFLAVINE (B2) 2MG

PYRIDOXINE HCL (B6) 2MG

NICOTINAMIDE 20MG

3. Pharmaceutical form

Oral Solution

4. Clinical particulars

4.1 Therapeutic indications

Oral prophylactic and therapeutic treatment of vitamin B complex deficiency.

4.2 Posology and method of administration

Prophylactic Children up to 1 year, One 5ml spoonful daily up to 12 years, One 5ml spoonful twice daily

Adults and elderly;

One 5ml spoonful three times daily

Therapeutic Children;

up to 1 year, One 5ml spoonful three times daily up to 12 years, Two 5ml spoonfuls three times daily

Adults and elderly;



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Two to three 5ml spoonfuls three times daily Or as prescribed by a doctor

4.3 Contraindications

Known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

No special warnings.

4.5 Interaction with other medicinal products and other forms of interaction

The pyridoxine hydrochloride may reduce the effectiveness of levodopa.

4.6 Pregnancy and lactation

Considered safe in the recommended dose.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

None known

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions

4.9 Overdose

Not applicable.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Vitamin B Complex.



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Thiamine Hydrochloride (Vit B1): A water soluble vitamin. It is a co-enzyme for carbohydrate metabolism.

Riboflavine (Vit B2): A water soluble vitamin converted in the body to flavine mononucleotide and flavine adenine dinucleotide and then involved as co-enzymes in oxidative and reductive metabolic processes.

Nicotinamide: A water soluble vitamin considered part of the Vitamin B group. Converted to Nicotinamide Adenine Dinucleotide and Nicotinamide Adenine Dinucleotide Phosphate in the body, both of which are co-enzymes important in electron transfer in respiratory reactions.

Pyridoxine Hydrochloride (Vit B6): A water soluble vitamin. Involved in carbohydrate and fat metabolism, but also important in haemoglobin formation.

5.2 Pharmacokinetic properties

All the actives are water soluble vitamins. Quantities in excess of the bodies requirements are excreted either unchanged or as metabolites, mainly in the urine but to a lesser extent also in the faeces.

5.3 Preclinical safety data

None stated

6. Pharmaceutical particulars

6.1 List of excipients

NA SACCHARINE

PROPYL PARABEN

METHYL PARABEN

NATROSOL

PROPYLENE GLYCOL



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GLYCERINE

SORBITOL

STRAWBERRY FLAVOUR

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C

6.5 Nature and contents of container

Bottle:	Amber PET
Closures:	28mm ROPP, tamper evident, child resistant.
Pack Sizes:	100ml X 60. 2L X 6

6.6 Special precautions for disposal and other handling

No special requirements.



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Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required (these should be disposed of in line with local requirements). These measures will help to protect the environment.

7. Marketing authorisation holder

UGOLAB PRODUCTIONS NIG. LTD

157/159 CLUB ROAD, BOMPAI INDUS LAYOUT, KANO,

KANO STATE.

NIGERIA.

8. Marketing authorisation number(s)

04-5112

9. Date of first authorisation/renewal of the authorisation

08/10/2010

10. Date of revision of the text

Not Applicable

Company Contact Details

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