



**National Agency for Food & Drug Administration &
Control
(NAFDAC)**

**Registration & Regulatory Affairs
(R & R) Directorate**

**SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
FIDSON B.CO SYRUP**

1. NAME OF THE MEDICINAL PRODUCT

Fidson B.Co syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains

Thiamine Hydrochloride	5.00 mg
Riboflavin Sodium Phosphate	2.74 mg
Nicotinamide	20.00 mg
Pyridoxine Hydrochloride	2.00 mg

3. PHARMACEUTICAL FORM

Oral Solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adults

Diazepam is an anxiolytic, anticonvulsant and central muscle-relaxant. Diazepam is used to

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

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

No special warnings.

4.6 Fertility, Pregnancy and breast-feeding

Pregnancy

Considered safe in the recommended dose.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

None known

4.9 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vitamin B Complex.

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

Riboflavine Sodium Phosphate (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

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

6.4 Special precautions for storage

Store in the original package.

Store below 30°C. Keep medicine away from direct sunlight

Keep all medicine out of the reach of children.

6.5 Nature and contents of container

100ml amber glass bottle, placed in an inner carton with insert

6.6 Special precautions for disposal

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. SUPPLIER AND MANUFACTURER

Fidson healthcare PLC,

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Sango Ota, Ogun state

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