IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0007/061/001
Case No: 2066850

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Boehringer Ingelheim Limited

Ellesfield Avenue, **Bracknell**, **Berkshire RG12 8YS**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Pharmaton Kiddi Oral Solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **10/07/2009**.

Signed on behalf of the Irish Medicines Board this

_____

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pharmaton Kiddi Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 7.5 ml contains:

Lysine hydrochloride	150.0 mg
Calcium glycerophosphate 50% solution corresponding to:	1530.0 mg
Calcium	65.0 mg
Phosphorus	100.0 mg
Thiamine hydrochloride (Vitamin B1)	1.5 mg
Riboflavine phosphate sodium (Vitamin B2 phosphate)	1.7 mg
Pyridoxine hydrochloride (Vitamin B6)	3.0 mg
Cholecalciferol (Vitamin D3)	7.5 microgram (300 IU)
alpha-Tocopherol acetate (Vitamin E)	7.5 mg
Nicotinamide (Vitamin PP)	10.0 mg
Dexpanthenol	5.0 mg

Each 7.5ml also contains 8.96mg sodium (corresponding to 0.390 mmol) and 0.141 mg of ethanol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution
A viscous, clear to slightly opalescent orange solution with an orange odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a supplement for persons requiring a dietary adjunct in convalescence, loss of appetite and in the correction of specific vitamin deficiencies.

4.2 Posology and method of administration

The recommended doses are:

Children 1 to 5 years:	7.5 ml daily.
Children over 5 years and adults:	15 ml per day.

Pharmaton Kiddi should be taken ½ to 1 hour before meals, ideally before breakfast or lunch.
Pharmaton Kiddi may be diluted with water or mixed with food.

Pharmaton Kiddi may show natural turbidity which is due to the fruit concentrate. This does not impair its efficacy.
Shake well before use.

4.3 Contraindications

Pharmaton Kiddi should not be taken:

- In cases of existing disorders of calcium metabolism, such as hypercalcaemia and hypercalciuria.
- In cases of hypersensitivity to any of the ingredients in the product.
- In cases of renal insufficiency.
- Concomitantly with other products containing vitamin D.
- In cases of hypervitaminosis of vitamin D.

4.4 Special warnings and precautions for use

Allowances for vitamin D from other sources should be made as excessive amounts of vitamin D may be harmful.

Pharmaton Kiddi should not be taken over a prolonged period in a dosage exceeding the recommended one.

Prolonged excessive ingestion of vitamin D can lead to hypervitaminosis states which may occur if foods high in this vitamin, (for example liver), are ingested in association with the recommended doses of this product.
Pharmaton Kiddi contains 2.52g of sorbitol per maximum recommended daily dose of 15ml.
Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

At the recommended dosage, no interactions with other drugs have been reported.

4.6 Pregnancy and lactation

No controlled studies in either animal or humans using Pharmaton Kiddi at the recommended doses in pregnant or lactating women are available.

Vitamin D given during the last trimester of pregnancy may cause hypercalcaemia in infants.

It is advised that if possible women receiving vitamin D do not breastfeed their infants as this may lead to the development of hypercalaemia in the infant.

4.7 Effects on ability to drive and use machines

No effects on ability to drive and use machines are known.

4.8 Undesirable effects

At the product’s recommended dosage no significant side-effects have been reported.

4.9 Overdose

Overdosage of Pharmaton Kiddi may result in toxicity. This is a result of the toxicity of the liposoluble vitamin D and the water-soluble vitamin B6. Prolonged daily intake of an overdosage (50 ml or more) of Pharmaton Kiddi may result in toxicity from the lipid-soluble vitamin D and the water-soluble Vitamin B6.

Such overdosage may cause symptoms of vitamin D overdosage such as vomiting, headache and diarrhoea and may also induce hypercalcaemia resulting in constipation. Such overdose of vitamin B6 may cause peripheral neuropathy resulting in neurological symptoms such as hyperaesthesia, paraesthesia and muscle weakness.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

An unbalanced or deficient diet may not provide all the necessary vitamins and minerals which children require. Vitamins and minerals correct and prevent impairment of cell metabolism in situations of increased demands or inadequate diet. Insufficient supply of essential substances which the body is unable to synthesise itself, may cause debility, tiredness, decrease in vitality, reduced resistance to and delayed recovery from illness.

Lysine is an essential amino acid which improves growth and liver function and helps make new protein and bone. In countries in which cereals and potatoes are the main foods, the body can get too little lysine. Cooking, baking and deep freezing can lead to loss of lysine from foods. Lysine deficiency leads to a reduction in protein synthesis and a decrease in enzymatic activity in the liver and pancreas. Loss of appetite can be a sign of lysine deficiency. In children, lysine is the amino acid most often inadequately supplied.

The action of lysine is supplemented by the B-complex vitamins which are necessary for normal metabolic functions including metabolism of protein, fat and carbohydrate.

Calcium and phosphorus are essential for the formation of bone mass.

Vitamin D is required for the absorption and utilisation of calcium and phosphorus and therefore contributes to the development and maintenance of healthy bones and teeth and the functioning of the muscles and nerves.

5.2 Pharmacokinetic properties

There are no data available on the pharmacokinetics of Pharmaton Kiddi.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol (E420)
Carmellose sodium
Orange essence
Polysorbate 80
Polysorbate 20
Saccharin sodium
Potassium sorbate (E202)
Sodium benzoate (E211)
Citric acid monohydrate
Disodium edetate
Ascorbic acid
Ethanol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the bottle tightly closed.

6.5 Nature and contents of container

100ml & 200ml brown glass bottles sealed with aluminium ROPP caps. The bottles are further packaged into cardboard cartons. The final packaging contains a plastic measuring cup.
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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 7/61/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 April 2001

Date of last renewal: 06 April 2006

10 DATE OF REVISION OF THE TEXT

July 2006