

*For the use only of Registered Medical Practitioners or a Hospital or a Laboratory*

## **COBADEX SYRUP**

### **Vitamin B<sub>12</sub>-B Complex Liquid**

#### **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 5 ml (one teaspoonful) contains:

Vitamin B <sub>1</sub> IP	5 mg
Vitamin B <sub>2</sub> IP	2.5 mg
Vitamin B <sub>6</sub> IP	1.5 mg
Nicotinamide IP	50 mg
D-Panthenol IP	5 mg
Vitamin B <sub>12</sub> IP	5 mcg
(Appropriate overages added)	

Colour: Carmoisine.

#### **PHARMACEUTICAL FORM**

Syrup

#### **CLINICAL PARTICULARS**

##### **Therapeutic Indications**

*COBADEX SYRUP* is indicated for treatment of deficiency states.

##### **Posology and Method of Administration**

###### ***Route of Administration***

For oral administration.

###### ***Adults***

One teaspoonful twice daily.

*COBADEX SYRUP* is not recommended for therapeutic use in children.

###### **Elderly**

There are no relevant data available.

###### **Renal impairment**

There are no relevant data available.

## **Hepatic impairment**

There are no relevant data available.

## **Contraindications**

Product is contraindicated in:

- Hypersensitivity to thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, nicotinamide, d-panthenol, cyanocobalamin, cobalt or any other ingredients.
- Haemophiliacs and in patients with ileus due to mechanical obstruction.

## **Special Warnings and Special Precautions for Use**

### *Vision disorders*

Cyanocobalamin (vitamin B<sub>12</sub>) should not be used for Leber's disease or tobacco amblyopia since these optic neuropathies may degenerate further.

### *Patients with folate deficiency*

This medicinal product should not be given to patients with suspected vitamin B<sub>12</sub> deficiency without first confirming the diagnosis. Regular monitoring of the blood is advisable. Use of doses greater than 10 micrograms daily may produce a haematological response in patients with folate deficiency; indiscriminate use may mask the precise diagnosis.

### *Investigations*

Large doses of riboflavin (vitamin B<sub>2</sub>) result in a bright yellow discoloration of the urine that may interfere with certain laboratory tests.

## **Interaction with Other Medicaments and Other Forms of Interaction**

### *Levodopa*

Pyridoxine reduces the effects of levodopa but this does not occur if a dopa decarboxylase inhibitor is also given.

### *Altretamine*

Pyridoxine reduces the activity of altretamine.

### *Phenobarbital, phenytoin*

Pyridoxine may decrease serum concentrations of phenobarbital and phenytoin.

### *Hydralazine, isoniazid, penicillamine*

Hydralazine, isoniazid, penicillamine may increase the requirements for pyridoxine.

### *Oral contraceptives*

Serum concentration of vitamin B<sub>6</sub>, vitamin B<sub>12</sub> may be decreased by use of oral contraceptives.

### *Neomycin, aminosalicylic acid, histamine H<sub>2</sub>-antagonists, omeprazole, colchicine*

Absorption of the vitamin B<sub>12</sub> from the gastrointestinal tract may be reduced by neomycin, aminosalicylic acid, histamine H<sub>2</sub>-antagonists, omeprazole, and colchicine.

### *Chloramphenicol*

Parenteral chloramphenicol may attenuate the effect of vitamin B<sub>12</sub> in anaemia.

### *Carbamazepine*

Concurrent use of carbamazepine and nicotinamide may result in an increased risk of carbamazepine toxicity.

## **Pregnancy and Lactation**

### ***Fertility***

There are no relevant data available.

### ***Pregnancy***

This medicinal product should be applied to pregnant women only if the potential benefit justifies the potential risk to the fetus.

### ***Lactation***

This product is distributed into breast milk. The negative effect for the child is thought to be unlikely when therapeutic doses are adhered to. A higher dose of vitamin B<sub>6</sub> may inhibit the production of breast milk in individual cases. It is considered that use of this medicinal product is usually compatible with breastfeeding but infant risk cannot be ruled out.

## **Effects on Ability to Drive and Use Machines**

There are no relevant data available.

## **Undesirable Effects**

### ***Clinical Trial Data***

There are no relevant data available.

### ***Post Marketing Data***

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency.

Frequencies are defined as:

Very common  $\geq 1/10$

Common  $\geq 1/100$  to  $< 1/10$

Uncommon  $\geq 1/1000$  to  $< 1/100$

Rare  $\geq 1/10000$  to  $< 1/1000$

Very rare  $< 1/10000$

Not known (cannot be estimated from the available data).

*Immune system disorders*

*Not known:* hypersensitivity reactions

## **Overdose**

### *Symptoms and signs*

Excess vitamin B is readily excreted; therefore no serious problems are anticipated for the administration of vitamin B in this form.

Prolong use of pyridoxine in a dose of about 200 mg may lead to neurotoxic effects (severe sensory neuropathy).

### *Treatment*

The treatment consists of product withdrawal and symptomatic treatment, if necessary.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

## **PHARMACOLOGICAL PROPERTIES**

### **Pharmacodynamic Properties**

Pharmacotherapeutic group: Vitamin B-complex, plain; ATC Code: A11EA.

### *Mechanism of Action and Pharmacodynamic Effects*

The vitamin B-complex comprises a group of water-soluble factors more or less closely associated in their natural occurrence. It is known that nearly every vitamin of the B-complex forms part of a co-enzyme essential for the metabolism of protein, carbohydrate or fatty acid.

### **Pharmacokinetic Properties**

There are no relevant data available.

### **Clinical Studies**

Not relevant for this product.

## **Preclinical Safety Data**

There are no relevant data available.

## **PHARMACEUTICAL PARTICULARS**

### **List of Excipients**

Sugar, methyl hydroxybenzoate, propyl hydroxybenzoate, colour carmoisine ,flavour Abrac S 1087 and purified water.

### **Incompatibilities**

There are no relevant data available.

### **Shelf Life**

The expiry date is indicated on the label and packaging.

### **Special Precautions for Storage**

Store in well closed containers at temperature below 30<sup>0</sup> C. Protect from direct sunlight.

Keep out of reach of children.

### **Nature and Specification of Container**

Amber glass bottle.

### **Instructions for Use/ Handling**

There are no special requirements for use or handling of this product.

### **For further information please contact:**

GlaxoSmithKline Pharmaceuticals Limited.

### **Registered Office:**

Dr. Annie Besant Road, Worli  
Mumbai 400 030, India.

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*Adapted from Thiamine hydrochloride (Vitamin B<sub>1</sub>), Riboflavin (Vitamin B<sub>2</sub>), Pyridoxine hydrochloride (Vitamin B<sub>6</sub>), Nicotinamide (Vitamin PP), D-Panthenol (Vitamin B<sub>5</sub>), Cyanocobalamin (Vitamin B<sub>12</sub>) NCDS 01 dated 25 January 2017.*