

## **SUMMARY OF PRODUCT CHARACTERISTICS G-GLUTAMIN TABLETS**

### **1. NAME OF THE MEDICINAL PRODUCT**

**G-Glutamin**

### **2. COMPOSITION**

Each film coated tablet contains:

L-Glutamic Acid BP 250 mg,

Thiamine Hydrochloride (Vit.B1) BP 10 mg,

Pyridoxine Hydrochloride (Vit.B6) BP 3 mg,

Cyanocobalamin (Vit.B12)(added as 0.1 % triturate) 10 mcg,

Excipients

For full list of excipients refer section 6.1.

### **3. Pharmaceutical form:**

Tablets

### **4. Clinical particulars:**

#### **4.1 Therapeutic indications**

Peripheral Neuropathy

ADHD in adults

#### **4.2 Posology and method of administration**

1 to 2 tablets 2 to 3 times a day OR as directed by the physician.

#### **4.3 Contraindications**

Hypersensitivity to the active substance(s) or to any of the excipients

Congenital abnormality of amino acid metabolism.

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

Do not exceed the stated dose

Keep out of the reach of children

If symptoms persist, consult your doctor

Use with caution in hepatic or renal insufficiency

#### **4.5 Interaction with other medicinal products and other forms of interaction**

The thiamine antagonists thiosemicarbazone and 5-fluorouracil can neutralise the effect of thiamine. Patients using any of these treatments may need their thiamine dose adjusted. Thiamine could give false positive results for urobilinogen determination by the Ehrlich's reaction. High doses of thiamine may interfere with spectrophotometric assays of theophylline plasma concentration.

Many drugs may alter the metabolism or bioavailability of pyridoxine, including isoniazid, penicillamine and oral contraceptives, which may increase the requirements for pyridoxine.

Pyridoxine hydrochloride may reduce the effect of levodopa, a drug used in the treatment of Parkinsons Disease unless a dopa decarboxylase inhibitor is also given

Absorption of cyanocobalamin may be reduced by Para-aminosalicylic acid, colchicine, biguanides, neomycin, cholestyramine, potassium chloride, methyl dopa, and cimetidine.

Patients treated with chloramphenicol may respond poorly to cyanocobalamin

Serum levels of cyanocobalamin may be lowered by oral contraceptives. These interactions are unlikely to have clinical significance.

Anti-metabolites and most antibiotics invalidate vitamins B12 assays by microbiological techniques.

#### **4.6 Fertility, pregnancy and lactation**

This product is not intended for use in pregnant or lactating women.

#### **4.7 Effects on ability to drive and use machines**

No studies on the effect on the ability to drive and use machines have been performed. However, patients should be cautioned to see how they react before driving or operating machinery

#### **4.8 Undesirable effects**

Mild gastrointestinal events such as nausea, vomiting, diarrhoea, and abdominal pain have been reported. Allergic and anaphylactic reactions, with symptoms of pruritus, urticaria, itching, hives, angioedema, abdominal pain, respiratory distress, tachycardia, palpitations, and shock have been reported in single cases. Long term administration of large doses of pyridoxine is associated with the development of severe peripheral neuritis. Sensitisation to cyanocobalamin is rare, but may present as an itching exanthema, and exceptionally as anaphylactic shock. Acneform and bullous eruptions have been reported rarely

#### **4.9 Overdose**

Overdose with this route of administration is unlikely. A suspected overdose should be treated symptomatically.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

##### **Glutamic acid**

Glutamic acid is an important amino acid which serves as nitric oxide and carbon supplier and is also an important element for building and maintaining muscles. Glutamine also protect brain from toxic effects of ammonia. This protection against cell toxin damage to brain functions and improves long term and short term memory. Glutamine improves production of gamma-amino butyric acid (GABA) which is an important neurotransmitter that can bring natural tranquilization.

##### **Vitamin B1 (Thiamine)**

Thiamine (as the coenzyme, thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a co-enzyme in the direct oxidative pathway of glucose metabolism. In thiamine deficiency, pyruvic and lactic acids accumulate in the tissues. The pyruvate ion is involved in the biosynthesis of acetylcholine via its conversion to acetyl co-enzyme A through a thiamine-dependent process. In thiamine deficiency, therefore, there are effects on the central nervous system due either to the effect on acetylcholine synthesis or to the lactate and pyruvate accumulation. Deficiency of thiamine results in fatigue, anorexia, gastro-intestinal disturbances, tachycardia, irritability and neurological symptoms. Gross deficiency of thiamine (and other Vitamin B group factors) leads to the condition beri-beri.

##### **Vitamin B6 (Pyridoxine)**

Pyridoxine, once absorbed, is rapidly converted to the co-enzymes pyridoxal phosphate and pyridoxamine phosphate which play an essential role in protein metabolism. Convulsions and hypochromic anaemia have occurred in infants deficient in pyridoxine.

### **Vitamin B12 (Cyanocobalamin)**

Vitamin B12 is present in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerisation of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B12 interferes with haemopoiesis and produces megaloblastic anaemia.

## **5.2 Pharmacokinetic properties**

### **Glutamic acid**

Glutamic acid is a non-essential amino acid which is degraded readily in the body to form glutamine (levoglutamide). Glutamic acid and glutamine are used as dietary supplements.

### **Vitamin B1 (Thiamine)**

Thiamine is absorbed from the gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body's requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.

### **Vitamin B6 (Pyridoxine)**

Pyridoxine is absorbed from the gastro-intestinal tract and converted to the active pyridoxal phosphate which is bound to plasma proteins. It is excreted in the urine as 4-pyridoxic acid.

### **Vitamin B12 (Cyanocobalamin)**

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B12 showed it was quickly taken up by the intestinal mucosa and held there for 2 - 3 hours. Peak concentrations in the blood and tissues did not occur until 8 - 12 hours after dosage with maximum concentrations in the liver within 24 hours. Cobalamins are stored in the liver, excreted in the bile and undergo enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.

## **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the Summary of Product Characteristics.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipient(s)**

Maize Starch

Methyl paraben

Propyl paraben

Povidone

Purified talc

Magnesium Stearate

Wincoat WT-01308 Red

Isopropyl alcohol

Dichloromethane

**6.2 Incompatibilities**

Not any

**6.3 Shelf life**

24 months

**6.4 Special precautions for storage**

Keep in cool and dry place, Protect from light.

**6.5 Nature and contents of container**

One Blister of 30 tablets packed in carton along with pack insert.

**7. MARKETING AUTHORISATION HOLDER:**

BLISS GVS PHARMA LTD.

102, Hyde Park, Saki Vihar Road, Andheri (East), Mumbai-400 072