

## Summary of Product Characteristics

1. **Name of the medicinal product** : AMINOTOP SYRUP (Multivitamin & Amino Acids Syrup)

### 2. Qualitative and Quantitative composition:

#### Composition:

Each 15ml (One Teaspoonful) contains:

L-Arginine Hydrochloride USP.....	13.28 mg
L-Histidine Hydrochloride Monohydrate USP .....	3.71 mg
L-Leucine USP .....	18.3 mg
L-Isoleucine USP.....	5.9 mg
L-Lysine Hydrochloride USP.....	25 mg
L-Methionine USP.....	9.2 mg
L-Phenylalanine USP.....	5 mg
L-Threonine USP.....	4.2 mg
L-Tryptophan USP.....	5 mg
L-Valine USP.....	6.7mg
Vitamin A Concentrate (Oil form)BP.....	2500 IU
Cholecalciferol BP.....	200 IU
Alpha Tocopheryl Acetate BP.....	7.5 IU
Thiamine Hydrochloride BP.....	5.0 mg
Riboflavin (as Riboflavin Sodium Phosphate) BP....	3.0 mg
Nicotinamide BP.....	25 mg
Calcium Pantothenate BP.....	5 mg
Pyridoxine Hydrochloride BP.....	1.5 mg
Cyanocobalamin BP.....	2.5 mcg
Ascorbic Acid BP.....	40 mg
Folic Acid BP.....	0.75 mg

Colour: Approved colour used

Flavored syrupy Base.....q.s

Overages of Vitamins added to compensate possible loss on Storage

### 3. Pharmaceutical Form: Oral Liquid.

### 4. Clinical Particulars:

#### 4.1 Therapeutic Indications

AMINOTOP SYRUP is used as a supplement in the treatment of conditions associated with deficiency of certain B-complex vitamins, minerals and amino acids, such as severe infections, degenerative diseases, endocrine dysfunction, surgical procedures, injuries, burns, old age, beriberi, riboflavinosis or pellagra.

#### 4.2 Posology and method of administration:

Shake before use

Adults: 10 ml one to three times daily.

Children: 5 ml in a little water, four times a day.

## **Method of Administration**

For oral administration.

### **4.3 Contraindications**

Contraindicated in patients known to be hypersensitive to any of its components and in patients with hypervitaminosis.

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

Multivitamins are not recommended for the treatment of severe specific deficiencies of vitamins and minerals. While taking the multivitamins, both protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision.

Do not take on an empty stomach. Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.

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

The pyridoxine hydrochloride may reduce the effectiveness of levodopa & Folic acid can reduce the plasma concentration of phenytoin.

### **4.6 Pregnancy and Lactation:**

AMINOTOP SYRUP may be administered during pregnancy and lactation at the recommendation of the physician.

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

None known.

### **4.8 Undesirable effects:**

Generally multivitamin and multiminerals are well tolerated by the body. Sometimes, reactions could occur, but they disappear rapidly after continuous and regular use.

#### **Ascorbic Acid (C), Nicotinamide, Pyridoxine (B<sub>6</sub>), Riboflavin (B<sub>2</sub>) & Thiamine (B<sub>1</sub>)**

These water soluble vitamins are generally nontoxic compounds with a wide margin of safety, the excess amounts being rapidly excreted in the urine.

### **4.9 Overdose**

Seek emergency medical attention. Most commonly reported, symptoms of Vitamins & amino acid overdose include nausea and vomiting.

## **Symptoms and signs**

AMINOTOP SYRUP contains levels of vitamins which present little risk in overdose.

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## **5. Pharmacological Particulars:**

### 5.1 Pharmacodynamic properties

(i) **Pharmaco-therapeutic group:** Multivitamins and other minerals, incl. combinations

(ii) **ATC code:** A11AA03

#### Mechanism of action:

AMINOTOP SYRUP is an Essential Amino Acids & Vitamins Syrup. The pharmacokinetics of the active substances would not be different from those naturally derived by food orally. Amino acids stimulates would not be different from those naturally derived by food orally. Amino acids stimulates the secretion of neurotransmitters which are chemicals transmitting the message in the brain. They also facilitate the production of hormones such as insulin, enzymes that activate bodily functions. In addition, the amino acids are essentials for the repair and maintenance of organs such as glands, muscles, skin and nails.

### 5.2 Pharmacokinetic properties

The pharmacokinetics of the active substances would not be different from those naturally derived by food orally.

### 5.3 Pre-clinical Safety:

None stated.

## 6. Pharmaceutical Particulars:

#### List of Excipients:

Sodium Methyl Paraben	BP
Sodium Propyl Paraben	BP
Sodium Benzoate	BP
Citric Acid (Monohydrate)	BP
Sucrose	BP
Liquid Glucose	BP
Bronopol BP	BP
Arrow Gum Super	IHS
Di-Sodium EDTA	BP
Sodium Hydroxide	BP
Acrysol K-140 / Cresmer RH 40	IHS
Sodium Saccharine	BP
Propylene Glycol	BP
Sodium Metabisulphate	BP
Butylated Hydroxyanisole	BP
Butylated Hydroxytoluene	BP
Thio Urea	IHS
Colour Caramel	IHS
Chocolate Éclair M-6626 Flavour	IHS
Butter Scotch M-5282 Flavour	IHS
Purified Water	BP

**6.2 Incompatibilities:** None known.

**6.3 Shelf Life:** 24 months.

**6.4 Special Precautions for storage:**

Store below 30°C in a dry place. Protect from light.

**6.5 Nature and contents of container:**

200 ml amber colour round brute type glass bottle packed in a Carton along with the Pack Insert.

**6.6 Special precautions for disposal and other handling:**

None

**7. Marketing Authorization Holder:**

**GB PHARMA LIMITED**

Address: 65 Chatsworth Road,  
London NW24BG  
United Kingdom.

**8. Marketing Authorization Number: --**

**9. Date of first Authorization /renewal of the authorization: --**

**10. Date of revision of text: Dec.2020**

### **1.3.2 Product information leaflet**

Enclosed

### **1.3.3 Labelling (outer and inner labels)**

Enclosed

### **1.3.4 Samples of the product as per FDA sample schedule**

**Enclosed**

## **1.4 Regional summaries**

### **1.4.1 Quality Information Summary (QIS)**

Enclosed

## **1.5 Electronic review document**

Not applicable.