

Summary of Product Characteristics

1. Name of the medicinal product : AMINOTOP-C DROPS

(Amino Acids & Vitamin C Drops)

2. Qualitative and Quantitative composition:

Composition:

Each ml contains:

- L-Leucine USP3.66 mg
- L-Isoleucine USP.....1.18 mg
- L-Lysine Hydrochloride USP.....5.0 mg
- L-Phenylalanine USP1.0 mg
- L-Threonine USP0.85 mg
- L-Methionine USP1.84 mg
- L-Tryptophan USP.....1.0 mg
- L-Valine USP.....1.34 mg
- Ascorbic acid BP.....100 mg

In a flavoured syrup base..... q. s.

Colour: Approved colour Use

No.	Raw Materials	Specific- tion	Label claim / ml	% Overages	Quantity in /ml(mg)	Reason Adding for
Active Ingredients						
1	L-Leucine	USP	3.66 mg	10%	4.026	Active
2	L-Isoleucine	USP	1.18 mg	10%	1.298	Active
3	L-Lysine Hydrochloride	USP	5.0 mg	--	5.0	Active
4	L-Phenylalanine	USP	1.0 mg	5%	1.05	Active
5	L-Threonine	USP	0.85 mg	5%	0.893	Active
6	L-Methionine	USP	1.84 mg	5%	1.93	Active
7	L-Tryptophan	USP	1.0mg	5%	1.05	Active
8	L-Valine	USP	1.34mg	10%	1.47	Active

9	Vitamin C (Ascorbic Acid)	BP	100.0mg	40%	140.0	Active
Excipients						
10	Sodium Methyl Paraben	BP	--	Nil	2.0	Preservative
11	Sodium Propyl Paraben	BP	--	Nil	0.6	Preservative
12	Sodium Benzoate	BP	--	Nil	3.0	Preservative
13	Sodium Metabisulphite	BP	--	Nil	0.7	Antioxidant
14	Sodium Hydroxide	BP	--	Nil	32.0	Alkalizing agent
15	Di Sodium Phosphate	BP	--	Nil	0.7	Buffering agent
16	Sorbitol Solution 70%	BP	--	Nil	300.0	Sweetening agent
17	Glycerin	BP	--	Nil	400.0	Lubricant
18	Thio Urea	BP	--	Nil	1.0	Solubilizer
19	Arrow Gum Super	BP	--	Nil	3.0	Viscosity modifier
20	Enisweet (Stevia)	IH	--	Nil	1.0	Sweetening agent
21	Colour Caramel	IH	--	Nil	0.01	Colouring agent
22	Butter Scotch M-5282 Flavour	IH	--	Nil	0.002 ml	Flavouring agent
23	Purified Water BP	BP	q.s.	Nil	q.s.	Vehicle

Where, BP: British Pharmacopoeia; USP: United State Pharmacopoeia

3. Pharmaceutical Form: Oral Drops Solution

4. Clinical Particulars:

4.1 Therapeutic Indications

AMINOTOP-C DROPS is used for supplementation of essential amino acids with Vit C, low birth wt in infants, recurrent infections, formulae fed infants & prescorbutic symptoms.

AMINOTOP-C Drops is used as a supplement in the treatment of conditions associated with deficiency of certain amino acids and vitamins c such as scurvy, slow wound healing, anemia, easy bruising, shortness of breath, fatigue, nosebleed, gastrointestinal problem, frequent infection, dermatitis, chronic gingivitis, impaired formation and maintenance of collagen, impaired multiple hormonal function, increased risk of various cancer, vascular degeneration.

4.2 Posology and method of administration:

Infants: 0.3 ml (about 6 drops) twice daily

6 months -2 year: 0.3ml (about 6 drops three times daily)

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

None

Precautions

If you take any medication before you start this consults your Doctor or Pharmacist.

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

None.

4.6 Pregnancy and Lactation:

Not indicated.

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.

Vitamin C is likely safe for most people when taken by mouth in recommended doses. In some people, vitamin C might cause nausea, vomiting, heartburn, stomach cramps, headache, and other side effects.

Other undesirable effects of peritoneal dialysis related to the procedure: catheter site infection, catheter related complication, hypocalcaemia and peritonitis bacterial.

4.9 Overdose

Hyper vitaminosis may occur with an intake far in excess of the daily requirement and recommended dosage. The sign and symptoms include dry and pruritic skin desquamations, erythematous dermatitis, distributed hair growth, fissures of lips, pain and tenderness of bone hyperostosis, headache, papiloedema, anorexia, oedema, fatigue, irritability, hemorrhage, fibrosis, sclerosis of central vein cirrhosis. Intra cranial pressure, raised alkaline phosphate and hypocalcaemia have been reported.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties

(i) **Pharmaco-therapeutic group:** Amino Acids & Vitamin C combinations

(ii) **ATC code:** --

Mechanism of action:

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.

Ascorbic acid is a water soluble vitamin and a powerful antioxidant.

Vitamin C is essential for collagen formulation and tissue repair in the body. It is also involved in the utilization of carbohydrates, synthesis of lipids and proteins and the preservation of blood vessel integrity.

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
Sodium Metabisulphite	BP
Sodium Hydroxide	BP
Di Sodium Phosphate	BP
Sorbitol Solution 70%	BP
Glycerin	BP
Thio Urea	BP
Arrow Gum Super	BP
Enisweet (Stevia)	IH
Colour Caramel	IH
Butter Scotch M-5282 Flavour	IH
Purified Water BP	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:

30 ml in Amber colour Glass bottle packed in a Primary Carton along with the Dropper & 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: January 2021