BECOACTIN SYRUP

1.5.1 SUMMARY OF PRODUCT CHARECTERISTICS

1. NAME OF MEDICINAL PRODUCT
Becoactin Syrup

1.1 Strength
Each 5 ml (One teaspoonful) contains:

Cyproheptadine Hydrochloride U.S.P.	2 mg
Thiamine Hydrochloride B.P. (Vitamin B1)	1 mg
Riboflavin B.P. (Vitamin B2)	0.5 mg
Pyridoxine Hydrochloride B.P. (Vitamin B6)	0.5 mg
Niacinamide B.P.	10 mg
Cyanocobalamin B.P. (Vitamin B12)	1 mcg
Flavoured base	q.s.

1.2 Pharmaceutical form
Syrup

2. QUALITATIVE QUANTITATIVE FORMULA

Qualitative composition:

Each 5 ml (One teaspoonful) contains:

Cyproheptadine Hydrochloride U.S.P.	2 mg
Thiamine Hydrochloride B.P. (Vitamin B1)	1 mg
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Flavoured base	q.s.

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Quantitative composition:

ITEM	DRUG NAME	SCALE per 5 ML	STD QTY PER 1000 mL	FUNCTION
1	Thiamine Hydrochloride BP	1 mg	0.500 g	Active
2	Riboflavin BP	0.5 mg	0.150 g	Active
3	Pyridoxine Hydrochloride BP	0.5 mg	0.150 g	Active
4	Cyanocobalamin BP	1 mcg	0.500 mg	Active
5	Niacinamide BP (Nicotinamide)	10 mg	2.500 g	Active
6	Cyproheptadine Hydrochloride USP	2 mg	0.420 g	Active
7	Sucrose BP (Crystalline)	2500 mg	500.000 g	Sweetening agent
8	Sodium Methylparaben BP	9 mg	1.800 g	Preservative
9	Sodium Propylparaben BP	1 mg	0.200 g	Preservative
10	Citric Acid Monohydrate BP	24 mg	4.800 g	Buffering agent
11	Sodium Citrate Dihydrate BP	13 mg	2.600 g	Buffering agent
12	Sodium Hydroxide BP (Pellets)	0.214 mg	42.800 mg	Buffering agent
13	Propylene Glycol BP	200 mg	40.000 g	Vehicle
14	Sodium Benzoate BP	4.98 mg	0.996 g	Preservative
15	Sorbitol Solution 70% (Non-crystallizing) BP	1000 mg	200.000 g	Sweetening agent
16	Pineapple Flavor No.1	0.01 ml	2 .000 mL	Flavoring agent
17	Purified Water BP	q.s.	Approx.310.000 mL	Vehicle

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3. PHARMACEUTICAL FORM
Syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Appetite Stimulant

4.2 Posology and method of administration
As directed by Physician

4.3 Contraindications
Becoactin syrup is contraindicated in:
• Newborn or Premature infants
• Pregnancy & lactation
• In those patients who have shown hypersensitivity to any of the ingredients used in Becoactin Syrup.

4.4 Special warnings and precautions for use
Should not be used in children, pregnancy and lactating mothers.

4.5 Fertility, pregnancy and lactation
Pregnancy Category B:

Reproduction studies have been performed in rabbits, mice, and rats at oral or subcutaneous doses up to 32 times the maximum recommended human oral dose and have revealed no evidence of impaired fertility or harm to the fetus due to Cyproheptadine (Cyproheptadine hydrochloride). Cyproheptadine (Cyproheptadine hydrochloride) has been shown to be fetotoxic in rats when given by intraperitoneal injection in doses four times the maximum recommended human oral dose. Two studies in pregnant women, however, have not shown that Cyproheptadine (Cyproheptadine hydrochloride) increases the risk of abnormalities when administered during the first, second and third trimesters of pregnancy. No Teratogenic effects were observed in any of the newborns. Nevertheless, because the studies in humans cannot rule out the possibility of harm, Cyproheptadine (Cyproheptadine hydrochloride) should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from Cyproheptadine (Cyproheptadine hydrochloride), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother

4.6 Effects on ability to drive and use machines

None

4.7 Overdose

Do not exceed the recommended doses. In case of overdosage consult the physician immediately.

4.8 Interaction with other medicinal products and other forms of interactions

Monoamine oxidase inhibitors prolong and intensify the anticholinergic effects of antihistamines. Antihistamines may have additive effects with alcohol and other central nervous system depressants, e.g., hypnotics, sedatives, tranquilizers, antianxiety agents

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5. Pharmacological properties

5.1 Pharmacodynamic properties

Cyproheptadine competes with free histamine for binding at HA-receptor sites. This antagonizes the effects of histamine on HA-receptors, leading to a reduction of the negative symptoms brought on by histamine HA-receptor binding. Cyproheptadine also competes with serotonin at receptor sites in smooth muscle in the intestines and other locations. Antagonism of serotonin on the appetite center of the hypothalamus may account for Cyproheptadine's ability to stimulate appetite.

5.2 Pharmacokinetic properties

After a single 2 mg oral dose of ^{14}C-labeled Cyproheptadine HCI in normal subjects, given as tablets or syrup, 2-20% of the radioactivity was excreted in the stools. Only about 34% of the stool radioactivity was unchanged drug, corresponding to less than 5.7% of the dose. At least 40% of the administered radioactivity was excreted in the urine. No detectable amounts of unchanged drug were present in the urine of patients on chronic 12-20 mg daily doses of Cyproheptadine syrup. The principal metabolite found in human urine has been identified as a quaternary ammonium glucuronide conjugate of Cyproheptadine. Elimination is diminished in renal insufficiency.

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose BP (Crystalline)

Sodium Methylparaben BP

Sodium Propylparaben BP

Citric Acid Monohydrate BP

Sodium Citrate Dihydrate BP

Sodium Hydroxide BP (Pellets)

Propylene Glycol BP

Sodium Benzoate BP

Sorbitol Solution 70% (Non-crystallizing) BP

Pineapple Flavor No.1

Purified Water BP

6.2 Incompatibilities
None

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store below 30 ^{0}C. Protected from light.
Do not refrigerate. Keep medicines out of reach of children.

6.5 Nature and contents of container
Bottle of 200ml in a carton along with pack insert.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing site address

Marketing Authorization Holder
Registered office address: MEYER ORGANICS PVT. LTD.
A-177, Road no. 16/Z, Wagle Industrial Estate,
Thane, Maharashtra – 400604. INDIA

Manufacturing site Address:
Plant/Site: MEYER ORGANICS PVT. LTD.
10 D, 2nd Phase, Peenya Industrial Area,
Bangalore 560058. INDIA.

8. MARKETING AUTHORIZATION NUMBER
Rwanda FDA-HMP-MA-0691

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF REGISTRATION
30/12/2023

10. DATE OF TEXT REVISION
March 2024