SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

Becoactin Syrup

2. Quality and Quantitative Composition

Each mL contains:
Cyproheptadine Hydrochloride U.S.P.....0.4 mg
Thiamine Hydrochloride (Vit. B1) B.P.....0.2 mg
Riboflavin (Vit B2) B.P.....0.1 mg
Pyridoxine Hydrochloride (Vit B6) B.P.....0.1 mg
Niacinamide B.P.....2 mg
Cyanocobalamin (Vit B12) B.P.....0.2mcg

For full list of excipients, see section 6.1.

3. Pharmaceutical Form

Yellow coloured sweet liquid pleasantly flavoured with pineapple.

4. Clinical Particulars

4.1 Therapeutic indications

Appetite Stimulant.

4.2 Posology and method of administration

CHILDREN (2 to 6 Years): ½ teaspoon (2.5 ml) to 1 teaspoonful (5 ml) 2 or 3 times a day
CHILDREN (7 to 14 years): 2 teaspoonfuls (10 ml) 2 or 3 times a day **ADOLESCENTS & ADULTS:** 2 teaspoonfuls (10 ml) 3 times a day or as directed by the Physician.
Liquid for oral administration.

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 warning and precautions for use

Interference with diagnostic tests:
Cyproheptadine reduced hypoglycemia-induced growth hormone secretion, between 5 and 97% in healthy subjects. Hence it was suggested that if patients receiving cyproheptadine were given a pituitary function test that used growth

hormone response to insulin-induced hypoglycemia, then cyproheptadine therapy should be stopped before the test.

4.5 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.

4.6 Pregnancy and lactation

Becoactin syrup is contraindicated in pregnancy & lactation**.**

4.7 Effects on ability to drive and use machine

NA

4.8 Undesirable effects

Confusion, hallucinations, convulsions, restlessness, blurred vision, fainting, unusual or irregular pulse, wheezing, dry mouth, dry nose, drowsiness may observe. (often transient).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after Authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose

Do not exceed the recommended doses. In case of over dosage, consult the physician immediately.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Cyproheptadine is a piperidine antihistamine. Unlike other antihistamines, this drug also antagonizes serotonin receptors. This action makes Cyproheptadine useful in conditions such as vascular headache and anorexia. Cyproheptadine does not prevent the release of histamine but rather competes with free histamine for binding at HA-receptor sites. Cyproheptadine competitively antagonizes the effects of histamine on HA-receptors in the GI tract, uterus, large blood vessels, and bronchial smooth muscle. Most antihistamines possess significant anticholinergic properties, but Cyproheptadine exerts only weak anticholinergic

actions. Blockade of central muscarinic receptors appears to account for Cyproheptadine's antiemetic effects, although the exact mechanism is unknown. 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. Cyproheptadine also has been used to counter vascular headaches, which many believe are caused by changes in serotonin activity, however it is unclear how Cyproheptadine exerts a beneficial effect on this condition.

5.2 Pharmacokinetic Properties

Absorption: Well, absorbed after oral administration

Protein Binding: 96-99%

Metabolism: Hepatic (Cytochrome P-450 system and some renal.

Excretion: After a single 4 mg oral dose of14C-labelled cyproheptadine HCl in normal subjects, given as tablets 2% to 20% of the radioactivity was excreted in the stools. At least 40% of the administered radioactivity was excreted in the urine.

5.3 Preclinical safety Data

Product containing simple, widely used, well documented ingredients which are subjects of current pharmacopeia's so the above data is not required.

6. Pharmaceutical Particulars

6.1 List of excipients

Sucrose B.P
Sodium Methylparaben
B.P Sodium
Propylparaben B.P
Citric Acid Monohydrate
B.P Sodium Citrate
Dihydrate B.P Sodium
Hydroxide B.P
Propylene Glycol B.P
Sodium Benzoate B.P
Sorbitol Solution 70% (Non-Crystallizing)
B.P Pineapple Flavour No. 1
Purified Water B.P

BP: British Pharmacopoeia

6.2 Incompatibilities

Not Known

6.3 Shelf life

30 months

6.4 Special precautions for storage

Store below 30°C, in dry place, Protect from light. Keep medicines out of reach of children.

6.5 Nature and contents of container

Each carton should contain **200 ml BECOACTIN SYRUP** filled in a sealed, duly labelled PET bottle. A measuring cup should be fitted on the cap. An Insert is kept inside the carton.

7. Marketing Authorization Holder

MEYER ORGANICS PVT. LTD.
10 D, 2nd Phase,
Peenya Industrial
Area, Bangalore
560058.

8. Marketing Authorization number
H2007/506

9. Date of renewal of the authorisation
15/06/2026

10. Date of revision of the text
15/06/2026