MODULE -1
ADMINISTRATIVE INFORMATION FOR BECOACTIN TABLET

1.5.1 SUMMARY OF PRODUCT CHARECTERISTICS

1. NAME OF MEDICINAL PRODUCT
Becoactin Tablet

2. QUALITATIVE QUANTITATIVE FORMULA

ITEM	DRUG NAME	SCALE MG per tablet	STANDARD QUANTITY PER 1000 TABLETS	FUNCTION
I.	**MINERAL GRANULATION:**			
1.	Elemental Iron Use: Ferrous Fumarate BP	8 mg (24.336 mg)*	24.336 g	
2.	Elemental Zinc Use: Zinc Sulphate Monohydrate USP	6 mg (16.470 mg)*	16.470 g	
3.	Tartaric Acid BP	0.200 mg*	0.200 g	
4.	Microcrystalline Cellulose BP (PH 101)	15 mg*	15.000 g	
5.	Polyvinylpyrrolidone BP (PVP K – 30)	2.1 mg*	2.100 g	
6.	Purified Water BP	q. s.*$	Approx. 15.000 g	
II.	**CYPROHEPTADINE GRANULATION:**			
7.	Cyproheptadine Hydrochloride Anhydrous Use: Cyproheptadine Hydrochloride USP (Contains 3% Excess)	4 mg (4.334 mg)*[1]	4.464 g	
8.	Thiamine Nitrate BP (Contains 60% Excess)	2 mg	3.200 g	
9.	Riboflavin BP (Contains 10% Excess)	0.5 mg	0.550 g	
10.	Nicotinamide BP (Contains 20%	10 mg	12.000 g	

	Excess)			
11.	Pyridoxine Hydrochloride BP (Contains 30% Excess)	1 mg	1.300 g	
12.	Glycine BP (Contains 10% Excess)	40 mg	44.000 g	
13.	Maize Starch (Dried)	70 mg*	70.000 g	
14.	Dibasic Calcium Phosphate BP	340 mg*	340.000 g	
15.	Sodium Starch Glycolate BP	20 mg*	20.000 g	
16.	Polyvinylpyrrolidone BP (PVP K-30)	30 mg*	30.000 g	
17.	Methylene Chloride	q.s.*[$]	Approx. 55.000 g	
III.	**LUBRICATION:**			
18.	Vitamin B12 Use: Vitamin B12 Coated 0.1% (Contains 100% Excess)	1 mcg (1 mg)*	2.000 g	
19.	Sodium Starch Glycolate BP	20 mg*	20.000 g	
20.	Purified Talc BP	16 mg*	16.000 g	
21.	Magnesium Stearate BP	5 mg*	5.000 g	
IV.	**PROTECTIVE COATING:**			
22.	Insta Moistshield (IC – MS- 5950)	15.675*	15.675 g	
23.	Isopropyl Alcohol BP	q.s.*[$]	110.000 g	
24.	Methylene Chloride	q.s.*[$]	204.000 g	
V.	**SUGAR COATING:**			
25.	Instacoat Universal SFC White (Product Code :A15R00014)	q.s.	504.880 g	
26.	Purified Water BP	q.s.*[$]	Approx. 1.419 Kg	
VI.	**COLOUR COATING:**			
27.	Instacoat Universal Red (Product code: A05R03038)	36.219 mg*	36.219 g	
28.	Glycerin (Glycerol) BP	2.041 mg*	2.041 g	
29.	Purified Water BP	q.s.*[$]	Approx.	

			292.684 g	
VII.	**POLISHING SOLUTION:**			
30.	Instaglow White IG-001	3.5 mg*	3.500 g	
31.	Purified Water BP	q.s.*	Approx. 50.000 g	

NOTES:

* Quantities not to be disclosed. For company information only. Minor rounding incorporated.

[1] Added 3% excess as process excess.

[$] Solvents evaporate during processing

Theoretical weight gain targeted for Sugar Coating is Approx. 78.5% w/w

Theoretical weight gain targeted for Colour Coating is Approx. 3.2% w/w

Theoretical weight gain targeted for polishing Coating is 0.3% w/w

Theoretical weight of dried Mineral granules: 58.106 g / 1000 Tablets

Theoretical weight of dried Cyproheptadine granules: 525.514 g / 1000 Tablets

Theoretical weight of lubricated granules: 626.62 g / 1000 Tablets

Theoretical Compression Weight: 627.000 mg / Tablet

Theoretical Weight of Protective Coated Tablets: Approx. 643 mg / Tablet

Theoretical Weight of Sugar Coated Tablets: Approx. 1147 mg / Tablet

Theoretical Weight of Colour Coated Tablets: Approx. 1184 mg / Tablet

Theoretical Weight of Polished Sugar Coated Tablets: Approx. 1187 mg / Tablet ± 10%

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3. PHARMACEUTICAL FORM
Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Appetite Stimulant

4.2 Posology and method of administration
As directed by Physician

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

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.

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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.

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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.

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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.