SUMMARYOF PRODUCT CHARACTERISTICS

1. NAMEOF THEMEDICINAL PRODUCT

CYPRIGOLDPLUS[Cyproheptadine withMultivitamin Caplets]

2. QUALITATIVEANDQUANTITATIVECOMPOSITION

Eachfilmcoatedcapletcontains:

Cyproheptadine Hydrochloride(Anhydrous)BP	2 mg
Thiamine Hydrochloride BP	1.5mg
Riboflavin BP	1.5mg
Pyridoxine Hydrochloride BP	1 mg
Calcium Pantothenate BP	2.5 mg

3. PHARMACEUTICALFORM

FilmcoatedCapletfororal use.

4. CLINICALPARTICULARS

4.1. Therapeuticindications

Cyproheptadine HCL in Cyprigold Plus is indicated for the Anorexia (lack of appetite).

AnorexiaNervosa is a psychological condition where patient does not want to take food. Cyprigold Plus is indicated for loss of appetite, weight loss, and as adjunct toanti-tubercular and anti-retroviral regimensfor weight gain.

VitaminB1:Neededto processcarbohydrates, fats and protein.

VitaminB2:Neededto process amino acids and fats, help convert carbohydrates into the fuel pyridoxine hydrochloride (Vitamin B6).

Vitamin B6 is a constituent of the co-enzymes, pyridoxal pyrophosphate and pyridoxamine phosphate, both of which play an important role in protein metabolism.

CalciumPantothenate:isanutritionalsupplementandusuallyusedinconjunctionwithotherB groupvitamins.

4.2. Posologyand methodof administration Routeofadministration:Oral.

TheusualrecommendeddoseofCyprigoldPlusCapletinadultisonecaplet 2 to 3 timesinadayoras directedby the physician.

4.3.

ContraindicationsNewbornorPrematu

reInfants

Use of Cyprigold Plus is contraindicated in newborn or premature infants.

NursingMothers

Becauseofthehigherriskofantihistaminesforinfantsgenerallyandfornewbornsandprematureinparticular, antihistaminetherapyis contraindicated innursing mothers.

OtherConditions

Other contraindications to Cyprigold Plus include hypersensitivity to any ingredient of formulation, angle-closure glaucoma, stenosing peptic ulcer, symptomatic prostatic hypertrophy, bladder neck obstruction and pyloroduodenal obstruction.

4.4. Special warnings and special precautions for usePediatric Patients Overdosage ofantihistamines,particularlyininfantsandyoungchildren,mayproducehallucinations, central nervous system depression, convulsions, respiratory and cardiac arrest,and death. Antihistamines may diminish mental alertness; conversely, particularly, in theyoungchild,they may occasionallyproduce excitation.

CNSDepressants

AntihistaminesmayhaveadditiveeffectswithalcoholandotherCNSdepressants,e.g.,hypnotics,sedatives, tranquilizers,antianxiety agents.

ActivitiesRequiringMentalAlertness

Patientsshouldbewarnedaboutengaginginactivitiesrequiringmentalalertnessandmotorcoordination,such as driving a car or operating machinery.

Antihistaminesaremorelikelytocausedizziness,sedation,andhypotensioninelderlypatients.

PRECAUTIONS General

Cyproheptadinehasanatropine-likeactionand,therefore,shouldbeusedwithcautioninpatients with:

History of bronchial asthmaIncreased intraocular pressureHyperthyroidismCardiovascular diseaseHypertension

4.5. Interactions with other Drug products and other forms of interactionDrug Interactions

MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines.AntihistaminesmayhaveadditiveeffectswithalcoholandotherCNSdepressants,e.g.,hypnotics,sedatives, tranquilizers,antianxiety agents.

4.6. Pregnancy and lactation

Fertility

Cyproheptadine had no effect on fertility in a two-litter study in rats or a two generation studyinmice atabout 10 times the humandose.

Cyproheptadinedidnotproducechromosomedamageinhumanlymphocytesorfibroblasts *in vitro*; high doses (10-4M) were cytotoxic. Cyproheptadine did not have anymutagenic effect in the Ames microbial mutagen test; concentrations of above 500 mcg/plateinhibitedbacterial growth.

Pregnancy

PregnancyCategory B

Reproduction studies have been performed in rabbits, mice, and rats at oral or subcutaneousdoses up to 32 times the maximum recommended human oral dose and have revealed noevidence of impaired fertility or harm to the fetus due to Cyproheptadine. Cyproheptadine hasbeen shown to be fetotoxic in rats when given by intraperitoneal injection in doses four timesthe maximum recommended human oral dose. Two studies in pregnant women, however,have not shown that Cyproheptadine increases the risk of abnormalities when administeredduringthefirst,secondandthirdtrimestersofpregnancy.Noteratogeniceffectswereobserved in any of the newborns. Nevertheless, because the studies in humans cannot rule outthe possibility of harm, Cyproheptadine should be used during pregnancy only if clearlyneeded.

Lactation

Itisnotknownwhetherthisdrugisexcretedinhumanmilk.Becausemanydrugsareexcreted in human milk, and because of the potential for serious adverse reactions in nursinginfants from Cyproheptadine, a decision should be made whether to discontinue nursing or todiscontinuethe drug, taking intoaccounttheimportance of the drugtothe mother.

4.7. Effectson ability todrive and use machines

This product may cause drowsiness and somnolence. Patients receiving it should not drive oroperate machinery unless it has been shown that their physical and mental capacity remainsunaffected.

4.8. Undesirableeffects

Thereis noundesirableeffect observed.

4.9Overdose

Adverse events experienced in higher than recommended doses were similar to those seen atnormal doses. In the event of over dosage, general symptomatic and supportive measures areindicated asrequired.

5. PHARMACOLOGICALPROPERTIES 5.1.Pharmacodynamicproperties

Cyproheptadine is a piperidine antihistamine. Unlike other antihistamines, this drug alsoantagonizes serotonin receptors. This action makes Cyproheptadine useful in conditions suchasvascularheadacheandanorexia.Cyproheptadinedoesnotpreventthereleaseofhistamine but rather competes with free histamine for binding at HA-receptor sites. Cyproheptadinecompetitively antagonizes the effects of histamine on HA-receptors in the GI tract, uterus,large blood vessels, and bronchial smooth muscle. Most antihistamines possess significantanticholinergicproperties,butCyproheptadineexertsonlyweakanticholinergicactions. Blockade of central muscarinic receptors appears to account for Cyproheptadine's antiemeticeffects,although the exact mechanism is unknown.

Cyproheptadinealsocompeteswithserotoninatreceptorsitesinsmoothmuscleintheintestinesandotherlocations.Antagonismofserotoninontheappetitecenterofthehypothalamusmayaccountfor Cyproheptadine'sabilitytostimulateappetite.Cyproheptadine also has been used to counter vascular headaches, which many believe arecaused by changes in serotonin activity; however it is unclear how Cyproheptadine exerts abeneficialeffect on this condition.

5.2Pharmacokinetic Properties

Absorption

Wellabsorbedafteroraladministration.

Metabolism

Hepatic(cytochrome P-450system)andsome renal.

Elimination

Afterasingle4mgoraldoseof14C-labelledCyproheptadineHClinnormalsubjects,givenas tablets 2% to 20% of the radioactivity was excreted in the stools. At least 40% of theadministeredradioactivity was excreted inthe urine.

5.3.Preclinicalsafetydata

NotApplicable

6. PHARMACEUTICALPARTICULARS

6.1. Listof excipients

Maize Starch

Sucrose

Methyl hydroxybenzoate

Propyl hydroxybenzoate

Colloidal Anhydrous Silica

Purified Talc

Magnesium Stearate

Isopropyl Alcohol

6.2. Shelf life

24Months

6.4Specialprecautionsfor storage

Store at a temperature below 30°C away from direct sunlight.

Keep all medicines out ofreach of children.

6.5. Natureand contentsof container

3x 10Caplets inBlisterPack

6.6. Instructionfor useand handling Nospecialrequirements.

7. APPLICANT

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