SUMMARY OF PRODUCT CHARACTERISTICS FOR CYPRODAN TABLET

NAME OF THE MEDICINAL PRODUCT

1. Cyprodan Tablet (Cyproheptadine Hydrochloride 4 mg Tablets)

QUALITATIVE AND QUANTITATIVE COMPOSITION

2. Each Cyprodan Tablet contains cyproheptadine hydrochloride equivalent to 4 mg anhydrous cy proheptadine hydrochloride.

PHARMACEUTICAL FORM

3. White to off white round flat, uncoated tablet with beveled edged having one side CYPRODAN and other side DANA embossed with a score line.
4.

4.1. CLINICAL PARTICULARS

Therapeutic indications

Cyprodan Tablet (Cyproheptadine Hydrochloride 4 mg Tablets) is a serotonin and histamine antagonist with anticholi nergic and sedative properties. In allergy and pruritus: 'Cyproheptadine Hydrochloride 4 mg Tablets ' has a wide range of anti-allergic and antipruritic activity, and can be used successfully in the treatment of acute and chronic allergic and pruritic conditions, such as dermatitis, including neurodermatitis and neurodermatitis circumscripta; eczema; eczemat oid Dermatitis; dermatographism; mild, local allergic reactions to insect bites; hay fever and other seasonal rhinitis; pe rennial allergic and vasomotor rhinitis; allergic conjunctivitis due to inhalant allergens and foods; urticaria; angioneur otic oedema;drug and serum reactions; anogenital pruritus; pruritus of chicken pox. Cyproheptadine Hydrochloride 4 mg Tablets ' is indicated as adjunctive therapy to Adrenaline and other standard measures for the relief of anaphylactic reactions after The acute manifestations have been controlled. In migraine and vascular headache: 'Cyproheptadine H ydrochloride 4 mg Tablets' has been reported to have beneficial effects in a significant number of patients having vasc ular types of headache. Many patients who have responded inadequately to all other agents have reported amelioration of symptoms with 'Cyproheptadine Hydrochloride 4 mg Tablets '. The characteristic headache and feeling of malaise may disappear within an hour or two of the first dose.

4.2 Posology and method of administration

Route of administration: oral. There is no recommended dosage for children under 2 years old. 'Cyproheptadine

Hydrochloride 4 mg Tablets ' is not recommended for elderly, debilitated patients.

For the treatment of allergy and pruritus:

Dosage must be determined on an individual basis. The effect of a single dose Usually lasts for four to six hours. For continuous effective relief, the daily Requirement should be given in divided doses, usually three times a day, or as often as

Necessary to provide continuous relief. *Adults*: The therapeutic range is 4-20 mg (1 to 5 tablets) a day, most patie nts

Requiring 12-16 mg a day. It is recommended that dosage be initiated with 4 mg three times a day and then adjust ed according to the weight and response of the patient up to a maximum of 32 mg a day. *Children aged 7-14 year s*: Usually 4 mg two or three times a day, according to the patient's weight and response. If an additional dose is re quired, it should be given at bedtime. Maximum 16 mg a day.

Children aged 2-6 years: Initially 2 mg two or three times a day, adjusted according to the patient's weight and res ponse. If an additional dose is required, it should be given at bedtime. Maximum 12 mg a day.

For treatment of vascular headache and migraine

For both prophylactic and therapeutic use, an initial dose of 4 mg, repeated if necessary after half an hour. Patients who respond usually obtain relief with 8 mg, and this dose should not be exceeded within a 4- to 6-hour period.

Maintenance: 4 mg every four to six hours.

Use in the elderly: 'Cyproheptadine Hydrochloride 4 mg Tablets ' should not be used in elderly, debilitated patient s. Elderly patients are more likely to experience dizziness, sedation, and hypotension.

4.3 Contraindications

'Cyproheptadine Hydrochloride 4 mg Tablets' is contraindicated in: patients undergoing therapy for an acute asthmatic attack; newborn or premature infants; use in infants has been associated with apnoea, c yanosis and respiratory difficulty breast-feeding mothers; patients with known sensitivity to cyprohepta dine hydrochloride or

drugs with similar chemical structure; concurrent use with monoamine oxidase inhibitors; glaucoma; pat ients with pyloroduodenal obstruction, stenosing peptic ulcer, symptomatic prostatic hypertrophy, predi sposition to urinary retention or bladder neck obstruction; elderly, debilitated patients.

4.4 Special warnings and precautions for use

Antihistamines should not be used to treat lower respiratory tract symptoms, including those of acute asthma.

The safety and efficacy of 'Cyproheptadine Hydrochloride 4 mg Tablets' is not established in children under 2 ye ars old. Overdosage of antihistamines, particularly in infants and children, may produce hallucinations, central ner vous system depression, convulsions, respiratory and cardiac arrest, and death. Antihistamines may diminish ment al alertness; conversely, particularly in the young child, they may occasionally produce excitation. Patients should be warned against engaging in activities requiring motor co-ordination and mental alertness, such as driving a car or operating machinery (see section 4.7 'Effects on ability to drive and use machines'). Rarely, prolonged therapy with antihistamines may cause blood dyscrasias. Because 'Cyproheptadine Hydrochloride 4 mg Tablets' has an at ropine-like action, it should be used cautiously in patients with a history of bronchial asthma, increasing intra-ocul ar pressure, hyperthyroidism, cardiovascular disease, or hypertension. Patients with rare hereditary problems of ga lactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines. Antihistamines may have addi tive effects with alcohol and other CNS depressants, e.g. hypnotics, sedatives, tranquillisers and anti-anxiety agent s. Drugs with anti-serotonin activity, such as cyproheptadine, may interfere with serotonin-enhancing anti-depress ants including selective serotonin re-uptake inhibitors (SSRI's). This may result in possible recurrence of depressi on and related symptoms. Cyproheptadine may cause a false positive test result for tricyclic antidepressant drugs (TCA) when evaluating a drug screen (e.g. urine, serum). Because cyproheptadine and TCAs may produce similar overdose symptoms, physicians should carefully monitor patients for TCA toxicity in the event of combined over dose.

4.6 Fertility, Pregnancy and lactation

The use of any drug in pregnancy or in women of child-bearing age requires that the potential benefit of the drug s hould be weighed against possible hazards to the embryo and fetus. It is not known whether 'Cyproheptadine Hyd rochloride 4 mg Tablets ' is excreted in human milk, and because of the potential for serious adverse reactions in b reast-feeding infants from 'Cyproheptadine Hydrochloride 4 mg Tablets ', a decision should be made whether to di scontinue breast-feeding or to discontinue the drug, taking into account the importance of the drug to the mother (see Section 4.3 'Contra-indications').

4.7 Effects on ability to drive and use machines

This product may cause drowsiness and somnolence. Patients receiving it should not drive or operate machinery u nless it has been shown that their physical and mental capacity remains unaffected.

4.8 Undesirable effects

The side effects that appear frequently are drowsiness and somnolence. Many patients who initially complain of d rowsiness may no longer do so after the first three to four days of continuous administration. Side effects reported with antihistamines are:

Blood and lymphatic system disorders:

Haemolytic anaemia, leucopenia, agranulocytosis, thrombocytopenia

Immune system disorders:

Allergic manifestation of rash and oedema, anaphylactic shock

Metabolism and nutrition disorders:

Anorexia, increased appetite

Psychiatric disorders:

Confusion, restlessness, excitation, irritability, nervousness, insomnia, aggressive behaviour, hallucinations, hyste ria and euphoria

Nervous system disorders:

Sedation, sleepiness (often transient), dizziness, disturbed coordination, tremor, paraesthesiae, neuritis, convulsion s, faintness, headache

Eye disorders:

Blurred vision, diplopia

Ear and labyrinth disorders:

Acute labyrinthitis, tinnitus, vertigo

Cardiac disorders:

Palpitation, tachycardia, extra systoles

Vascular disorders:

Hypotension

Respiratory, thoracic and mediastinal disorders:

Thickening of bronchial secretions, dryness of nose and throat, tightness of chest and wheezing, nasal stuffiness, e pistaxis

Gastrointestinal disorder:

Dryness of mouth, epigastric distress, nausea, vomiting, diarrhoea, constipation

Hepato-biliary disorders:

Cholestasis, hepatic failure, hepatitis, hepatic function abnormality, jaundices

Skin and subcutaneous tissue disorders:

Urticaria, photosensitivity, excessive perspiration

Renal and urinary disorders:

Frequency and difficulty of micturition, urinary retention

Reproductive system and breast disorders:

Early menses

General disorders and administration site conditions:

Fatigue, rigors

Investigations:

Weight gain

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continue d monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yell ow Card in the Google Play or Apple App Store.

4.9 Overdose

Antihistamine over dosage reactions may vary from CNS depression or stimulation to convulsions respiratory and cardiac arrest and death, especially in infants and children. Atropine-like and gastro-intestinal symptoms may occ ur. If vomiting has not occurred spontaneously, it should be induced in the conscious patient with syrup of ipecac. If the patient cannot vomit, gastric lavage with isotonic or half isotonic saline is indicated, followed by activated c harcoal. Precautions against aspiration must be taken, especially in infants and children. Life-threatening CNS sig ns and symptoms should be treated appropriately. Saline cathartics usefully draw water into the bowel by osmosis to dilute bowel content rapidly. Central stimulants must not be used, but vasopressors may be used to counteract h ypotension.

5 PHARMACOLOGICAL PROPERTIES

5.1

Pharmacodynamic properties

Cyproheptadine hydrochloride is a serotonin and histamine antagonist with anticholinergic and sedative effects. A ntiserotonin and antihistamine drugs appear to compete with serotonin and histamine, respectively, for receptor sit es. Cyproheptadine hydrochloride antagonises the following effects of serotonin in laboratory animals: Bronchoco nstrictor (guinea-pig) Vasopressor (dog) Spasmogenic (isolated rat uterus) Oedema (rat) Lethal (hemophilus petus sis-treated mouse) In these effects it equals or surpasses the activity of many of the activities of specific serotonin antagonists, such as 1-Benzyl-2-methyl-5-methoxy-tryptame (BAS) and 1- Benzyl-2-methyl-5-hydroxy-tryptamin e (BMS), in contrast, specific anti-histamines, even the most potent, show little or no serotonin antagonism. Cypro heptadine hydrochloride antagonises or blocks the following effects of histamine in laboratory animals: Bronchoc onstrictor (guinea-pig) Vasopressor (dog) Spasmogenic (isolated rat uterus) Anaphylactic shock, active and passiv e (guinea-pig and mouse) Increased gastric secretion (Heidenhain pouch dog) It is unusual that cyproheptadine hy drochloride protects both the guinea-pigs and mice against anaphylactic shock. In guinea-pigs, the pulmonary asp ects of anaphylactic shock are attributable to the release of endogenous histamine and can be controlled by substa nces with specific anti-histamine activity. In mice however, where histamine release seems to be less important an d serotonin release may be involved, specific anti-histamines are of little value in protecting against anaphylaxis. Thus, the protective effect of cyproheptadine hydrochloride in mice may be an anti- serotonin effect. The inhibitor y effect of cyproheptadine in histamine-induced gastric secretion is also unusual as specific anti-histamines do not influence this effect. Cyproheptadine has appetite stimulation properties in laboratory animals.

5.2 Pharmacokinetic properties

After a single 4 mg oral dose of 14C-labelled cyproheptadine hydrochloride (Cyprodan Tablet) in normal subjects given as tablets or syrup, 2 to 20% of the radioactivity was excreted in the stools. Only about 34% of the stool rad ioactivity was unchanged drug, corresponding to less than 5.7% of the dose. At lease 40% of the administered radi oactivity was excreted in the urine. No significant difference in the mean urinary excretion exists between the tabl et and syrup formulations. No detectable amounts of unchanged drug were present in the urine of patients on chro nic 12-20 mg daily doses of Periactin syrup. The principle metabolite found in human urine has been identified as a quaternary ammonium glucuronide conjugate of cyproheptadine. Elimination is diminished in renal insufficienc y.

5.3 Preclinical safety data

No relevant information.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cyprodan tablets contain the following inactive ingredients:

Di calcium Phosphate, lactose, magnesium stearate , mazie starch, Talcum BP, Magnesium Stearate BP, Gelatin B P, Sodium Starch Glycolate BP, Sodium Methyl Hydroxy Benzoate BP and Sodium Propyl Hydroxy Benzoate BP

6.2 Incompatibilities

None known

6.3 Shelf life

3 years from the manufacturing date.

6.4 Special precautions for storage

Do not store above 30°C, protect from light and store in the original container.

6.5 Nature and contents of container

Blister Packing: 3 blisters of 10 Tablets each packed in printed mono cartons.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Dana Pharmaceuticals Ltd

Shiroro Dam Road, Maitumbi, Minna

Niger State.

8 MARKETING AUTHORISATION NUMBER(S)

B4 - 1093

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THEAUTHORISATION

Last renewed: 6th November, 2018

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5th November, 2023