PATIENT INFORMARION LEAFLET: INFORMATION FOR THE USER

RONANUTRA
(CYPROHEPTADINE TABLETS BP 4 MG)

Read all of this leaflet carefully before you start RONANUTRA using

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. WHAT RONANUTRA AND WHAT IT IS USED FOR

Perennial and seasonal allergic rhinitis

Vasomotor rhinitis

Allergic conjunctivitis due to inhalant allergens and foods

Mild, uncomplicated allergic skin manifestations of urticaria and angioedema.

Amelioration of allergic reactions to blood or plasma

Cold urticaria

Dermatographism

As therapy for anaphylactic reactions *adjunctive* to epinephrine and other standard measures after the acute manifestations have been controlled.

2. BEFORE YOU TAKE RONANUTRA

General

Cyproheptadine has an atropine-like action and, therefore, should be used with caution in patients with:
History of bronchial asthma
Increased intraocular pressure

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Hyperthyroidism
Cardiovascular disease
Hypertension

Information for Patients

Antihistamines may diminish mental alertness; conversely, particularly, in the young child, they may occasionally produce excitation. Patients should be warned about engaging in activities requiring mental alertness and motor coordination, such as driving a car or operating machinery.

Drug Interactions

MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines.

Antihistamines may have additive effects with alcohol and other CNS depressants, e.g., hypnotics, sedatives, tranquilizers, antianxiety agents.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term carcinogenic studies have not been done with cyproheptadine.

Cyproheptadine had no effect on fertility in a two-litter study in rats or a two generation study in mice at about 10 times the human dose.

Cyproheptadine did not produce chromosome damage in human lymphocytes or fibroblasts *in vitro*; high doses (10-4M) were cytotoxic. Cyproheptadine did not have any mutagenic effect in the Ames microbial mutagen test; concentrations of above 500 mcg/plate inhibited bacterial growth.

Pregnancy

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 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 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 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, 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.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of two have not been established.

Geriatric Use

Clinical studies of cyproheptadine HCl tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the

dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

3. HOW TO TAKE YOUR MEDICINE

DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND THE RESPONSE OF THE PATIENT.

Each tablet contains 4 mg of cyproheptadine hydrochloride.

Pediatric Patients
Age 2 to 6 years
The total daily dosage for pediatric patients may be calculated on the basis of body weight or body area using approximately 0.25 mg/kg/day or 8 mg per square meter of body surface (8 mg/m2).

The usual dose is 2 mg (½ tablet) two or three times a day, adjusted as necessary to the size and response of the patient. The dose is not to exceed 12 mg a day.

Age 7 to 14 years
The usual dose is 4 mg (1 tablet) two or three times a day adjusted as necessary to the size and response of the patient. The dose is not to exceed 16 mg a day.

Adults
The total daily dose for adults should not exceed 0.5 mg/kg/day. The therapeutic range is 4 to 20 mg a day, with the majority of patients requiring 12 to 16 mg a day. An occasional patient may require as much as 32 mg a day for adequate relief. It is suggested that dosage be initiated with 4 mg (1 tablet) three times a day and adjusted according to the size and response of the patient.

4. POSSIBLE SIDE EFFECTS

Adverse reactions which have been reported with the use of antihistamines are as follows:

Central Nervous System
Sedation and sleepiness (often transient), dizziness, disturbed coordination, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, paresthesias, neuritis, convulsions, euphoria, hallucinations, hysteria, faintness.

Integumentary
Allergic manifestation of rash and edema, excessive perspiration, urticaria, photosensitivity.

Special Senses
Acute labyrinthitis, blurred vision, diplopia, vertigo, tinnitus.

Cardiovascular
Hypotension, palpitation, tachycardia, extrasystoles, anaphylactic shock.

Hematologic
Hemolytic anemia, leukopenia, agranulocytosis, thrombocytopenia.

Digestive System
Cholestasis, hepatic failure, hepatitis, hepatic function abnormality, dryness of mouth, epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation, jaundice.

Genitourinary
Urinary frequency, difficult urination, urinary retention, early menses.

Respiratory
Dryness of nose and throat, thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

Miscellaneous
Fatigue, chills, headache, increased appetite/weight gain.

5. HOW TO STORE RONANUTRA

Store in a dry place below 30°C. Protect from light, heat & moisture.

6. FURTHER INFORMATION

What RONANUTRA contains:

- The active pharmaceutical ingredient(s) are CYPROHEPTADINE HYDROCHLORIDE BP.
- The other ingredient(s) are Maize starch, Dibasic calcium phosphate & Magnesium stearate.

What RONANUTRA looks like and contents of the pack:
White coloured, round, flat, uncoated tablets, having break line on one side and plain on other side.

50 x 10 Tab alu-pvc pack in a carton with pack insert.

Manufacturer

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