

Artica[®]

Hydroxyzine Hydrochloride

Description

Artica[®] is a preparation of Hydroxyzine Hydrochloride. Hydroxyzine is an anxiolytic antihistamine of the piperazine class which is a H₁ receptor antagonist. **Artica[®]** is not a cortical depressant, but its action may be due to a suppression of activity in certain key regions of the subcortical area of the central nervous system. Primary skeletal muscle relaxation has been demonstrated experimentally. Bronchodilator activity and anti-histaminic and analgesic effects have been demonstrated experimentally and confirmed clinically. An antiemetic effect, both by the apomorphine test and the veriloid test, has been demonstrated.

Indications and Uses

- For the management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses, and in histamine-mediated pruritus.
- For symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested.
- As a sedative when used as a premedication and following general anesthesia.

Dosage & administration

For pruritus:

Adult: Initially 25 mg at night increased if necessary to 25 mg 3–4 times daily

Child 12–18 years: Initially 25 mg at night, increased if necessary to 100 mg in 3–4 divided doses

Child 6–12 years: Initially 15–25 mg (1½ teaspoonfuls - 2½ teaspoonfuls) at night, increased if necessary to 50–100 mg daily in 3–4 divided doses

Child 6 months–6 years: Initially 5–15 mg (½ teaspoonfuls - 1½ teaspoonfuls) at night, increased if necessary to 50 mg daily in 3–4 divided doses

For symptomatic relief of anxiety and tension:

Adult: 50 - 100 mg four times daily

Children over 6 years: 50 - 100 mg (5 teaspoonfuls– 10 teaspoonfuls) daily in divided doses

Children under 6 years: 50 mg (5 teaspoonfuls) daily in divided doses

Note: 1 teaspoonful (5 ml) contains 10 mg Hydroxyzine Hydrochloride, USP

For used as a premedication and following general anesthesia:

Adult: 50- 100 mg

Children: 0.6 mg/kg of body weight

Use in patients with renal impairment

In case of renal impairment half of normal dose should be given.

Use in elderly

In the elderly, it is advised to start with half the recommended dose due to the prolonged action.

Use in pregnancy and lactation

Pregnancy: Clinical data in human beings are inadequate to establish safety in early pregnancy. Until such data are available, Hydroxyzine is contraindicated in early pregnancy.

Lactation: It is not known whether this drug is excreted in human milk. Since many drugs are so excreted, Hydroxyzine should not be given to nursing mothers.

Precautions

The potentiating action of Hydroxyzine must be considered when the drug is used in conjunction with central nervous system depressants such as narcotics, non-narcotic analgesics and barbiturates.

Therefore, when central nervous system depressants are administered concomitantly with Hydroxyzine, their dosage should be reduced. Since drowsiness may occur with use of this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery while taking Hydroxyzine. Patients should be advised against the simultaneous use of other CNS depressant drugs, and cautioned that the effect of alcohol may be increased.

Side effects

More common side effects include drowsiness, headache, psychomotor impairment, and antimuscarinic effects such as urinary retention, dry mouth, blurred vision, and gastrointestinal disturbances. Other rare side-effects of antihistamines include hypotension, palpitation, arrhythmias, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, hypersensitivity reactions (including bronchospasm, angioedema, and anaphylaxis, rashes, and photosensitivity reactions), blood disorders, liver dysfunction, and angle-closure glaucoma.

Drug interactions

Hydroxyzine may potentiate meperidine and barbiturates, so their use in pre-anesthetic adjunctive therapy should be modified on an individual basis. Atropine and other bella-donna alkaloids are not affected by the drug. Hydroxyzine is not known to interfere with the action of digitalis in any way and it may be used concurrently with this agent. Simultaneous administration of Hydroxyzine with monoamine oxidase inhibitors should be avoided.

Contraindications

Hydroxyzine is contraindicated in patients with a known hypersensitivity to Hydroxyzine or any of its ingredients.

Over dosage

The most common manifestation of Hydroxyzine overdosage is hypersedation. As in the management of over-dosage with any drug, it should be borne in mind that multiple agents may have been taken. If vomiting has not occurred spontaneously, it should be induced. Immediate gastric lavage is also recommended. General supportive care, including frequent monitoring of the vital signs and close observation of the patient, is indicated. Hypotension, though unlikely, may be controlled with intravenous fluids and Levarterenol or Metaraminol. Epinephrine should not be used as Hydroxyzine counteracts its pressor action. There is no specific antidote. It is doubtful that hemodialysis would be of any value in the treatment of overdosage with Hydroxyzine. However, if other agents such as barbiturates have been ingested concomitantly, hemodialysis may be indicated. There is no practical method to quantitate Hydroxyzine in body fluids or tissue after its ingestion or administration.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light.

Presentation

Artica[®] 10 mg tablet: Each coated tablet contains Hydroxyzine Hydrochloride USP 10 mg.

Artica[®] 25 mg tablet: Each coated tablet contains Hydroxyzine Hydrochloride USP 25 mg.

Artica[®] syrup: Each 5 ml syrup contains Hydroxyzine Hydrochloride USP 10 mg.

Package quantities

Artica[®] 10 mg tablet: Carton of 250 tablets in blister.

Artica[®] 25 mg tablet: Carton of 200 tablets in blister.

Artica[®] syrup: Bottle of 100 ml syrup.

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