

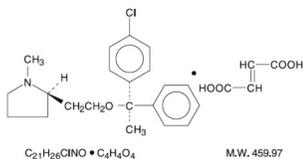
CLEMASTINE FUMARATE - clemastine fumarate tablet

Sandoz Inc.

Rx only

DESCRIPTION

Clemastine fumarate belongs to the benzhydryl ether group of antihistaminic compounds. The chemical name is (+)-2-[-2- [(p-chloro- α -methyl- α -phenylbenzyl) oxy] ethyl]-1-methylpyrrolidine hydrogen fumarate. It has the following structural formula:



Each tablet for oral administration contains 2.68 mg clemastine fumarate. Inactive ingredients include lactose (monohydrate), hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, and starch (corn).

CLINICAL PHARMACOLOGY

Clemastine fumarate is an antihistamine with anticholinergic (drying) and sedative side effects. Antihistamines appear to compete with histamine for cell receptor sites on effector cells. The inherently long duration of antihistaminic effects of clemastine has been demonstrated in wheal and flare studies. In normal human subjects who received histamine injections over a 24-hour period, the antihistaminic activity of clemastine reached a peak at 5 to 7 hours, persisted for 10 to 12 hours and, in some cases, for as long as 24 hours. Pharmacokinetic studies in man utilizing 3H and ^{14}C labeled compound demonstrates that: clemastine is rapidly and nearly completely absorbed from the gastrointestinal tract, peak plasma concentrations are attained in 2 to 4 hours, and urinary excretion is the major mode of elimination.

INDICATIONS AND USAGE

Clemastine fumarate tablets are indicated for the relief of symptoms associated with allergic rhinitis such as sneezing, rhinorrhea, pruritus, and lacrimation.

Clemastine fumarate tablets are also indicated for the relief of mild, uncomplicated allergic skin manifestations of urticaria and angioedema.

It should be noted that clemastine is indicated for the dermatologic indications at the 2.68 mg dosage level only.

CONTRAINDICATIONS

Use in Nursing Mothers

Because of the higher risk of antihistamines for infants generally and for newborns and prematures in particular, antihistamine therapy is contraindicated in nursing mothers.

Use in Lower Respiratory Disease

Antihistamines **should not** be used to treat lower respiratory tract symptoms including asthma.

Antihistamines are also contraindicated in the following conditions:

Hypersensitivity to clemastine fumarate or other antihistamines of similar chemical structure.

Monoamine oxidase inhibitor therapy (see Drug Interaction Section).

WARNINGS

Antihistamines should be used with considerable caution in patients with: narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, and bladder neck obstruction.

Use in Children

Safety and efficacy of clemastine fumarate have not been established in children under the age of 12 years.

Use in Pregnancy

Experience with this drug in pregnant women is inadequate to determine whether there exists a potential for harm to the developing fetus.

Use with CNS Depressants

Clemastine has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.)

Use in Activities Requiring Mental Alertness

Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc.

Use in the Elderly (approximately 60 years or older)

Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients.

PRECAUTIONS

General

Clemastine fumarate should be used with caution in patients with: history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease, and hypertension.

Drug Interactions

MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

ADVERSE REACTIONS

Transient drowsiness, the most common adverse reaction associated with clemastine fumarate, occurs relatively frequently and may require discontinuation of therapy in some instances.

Antihistaminic Compounds

It should be noted that the following reactions have occurred with one or more antihistamines and, therefore, should be kept in mind when prescribing drugs belonging to this class, including clemastine fumarate.

The most frequent adverse reactions are underlined.

1. *General:* Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose, and throat.
2. *Cardiovascular System:* Hypotension, headache, palpitations, tachycardia, extrasystoles.
3. *Hematologic System:* Hemolytic anemia, thrombocytopenia, agranulocytosis.
4. *Nervous System:* Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesias, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions.
5. *GI System:* Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
6. *GU System:* Urinary frequency, difficult urination, urinary retention, early menses.
7. *Respiratory System:* Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

OVERDOSAGE

Antihistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Atropine-like signs and symptoms: dry mouth; fixed, dilated pupils; flushing; and gastrointestinal symptoms may also occur.

If vomiting has not occurred spontaneously the conscious patient should be induced to vomit. This is best done by having him drink a glass of water or milk after which he should be made to gag. Precautions against aspiration must be taken, especially in infants and children.

If vomiting is unsuccessful gastric lavage is indicated within 3 hours after ingestion and even later if large amounts of milk or cream were given beforehand. Isotonic and 1/2 isotonic saline is the lavage solution of choice.

Saline cathartics, such as milk of magnesia, by osmosis draw water into the bowel and therefore, are valuable for their action in rapid dilution of bowel content.

Stimulants should **not** be used.

Vasopressors may be used to treat hypotension.

DOSAGE AND ADMINISTRATION

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

The recommended starting dose is 1.34 mg (1/2 tablet) twice daily. Dosage may be increased as required. Clemastine fumarate tablets are recommended for the dermatologic indications at the 2.68 mg dosage level only.

The maximum recommended dosage is 2.68 mg three times daily. Many patients respond favorably to a single dose which may be repeated as required, but not to exceed three tablets daily.

HOW SUPPLIED

Clemastine fumarate tablets, USP are available as:

2.68 mg: Round, white tablets, scored, debossed GG 160 on one side and plain on the reverse side and supplied as:

NDC 0781-1359-01 bottles of 100

NDC 0781-1359-05 bottles of 500

NDC 0781-1359-10 bottles of 1000

Store below 25°C. Dispense in a tight, light-resistant container.

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