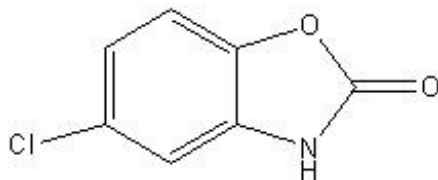


CHLORZOXAZONE - chlorzoxazone tablet
Novitium Pharma LLC

Chlorzoxazone Tablets, USP 500 mg
Novitium Pharma LLC

DESCRIPTION

Chlorzoxazone USP is a centrally acting skeletal muscle relaxant, available as tablets of 500 mg for oral administration. Its chemical name is 5-Chloro-2-benzoxazolinone, and its structural formula is:



$C_7H_4ClNO_2$
MW 169.57

Chlorzoxazone USP is a white or practically white, practically odorless, crystalline powder. Chlorzoxazone is slightly soluble in water; sparingly soluble in alcohol, in isopropyl alcohol, and in methanol; soluble in solutions of alkali hydroxides and ammonia.

Chlorzoxazone tablets contain the inactive ingredients Pregelatinized Starch, Croscarmellose Sodium, Microcrystalline Cellulose, Docusate Sodium, Sodium Benzoate, Colloidal Silicon dioxide, Magnesium Stearate.

CLINICAL PHARMACOLOGY

Chlorzoxazone is a centrally-acting agent for painful musculoskeletal conditions. Data available from animal experiments as well as human study indicate that chlorzoxazone acts primarily at the level of the spinal cord and subcortical areas of the brain where it inhibits multisynaptic reflex arcs involved in producing and maintaining skeletal muscle spasm of varied etiology. The clinical result is a reduction of the skeletal muscle spasm with relief of pain and increased mobility of the involved muscles. Blood levels of chlorzoxazone can be detected in people during the first 30 minutes and peak levels may be reached, in the majority of the subjects, in about 1 to 2 hours after oral administration of chlorzoxazone. Chlorzoxazone is rapidly metabolized and is excreted in the urine, primarily in a conjugated form as the glucuronide. Less than one percent of a dose of chlorzoxazone is excreted unchanged in the urine in 24 hours.

INDICATIONS & USAGE

Chlorzoxazone is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of this drug has not been clearly identified, but may be related to its sedative properties. Chlorzoxazone does not directly relax tense skeletal muscles in man.

CONTRAINDICATIONS

Chlorzoxazone is contraindicated in patients with known intolerance to the drug.

WARNINGS

Serious (including fatal) hepatocellular toxicity has been reported rarely in patients receiving chlorzoxazone. The mechanism is unknown but appears to be idiosyncratic and unpredictable. Factors predisposing patients to this rare event are not known. Patients should be instructed to report early signs and/or symptoms of hepatotoxicity such as fever, rash, anorexia, nausea, vomiting, fatigue, right upper quadrant pain, dark urine, or jaundice. Chlorzoxazone should be discontinued immediately and a physician consulted if any of these signs or symptoms develop. Chlorzoxazone use should also be discontinued if a patient develops abnormal liver enzymes (e.g., AST, ALT, alkaline phosphatase and bilirubin.)

The concomitant use of alcohol or other central nervous system depressants may have an additive effect.

Usage in Pregnancy

The safe use of chlorzoxazone has not been established with respect to the possible adverse effects upon fetal development. Therefore, it should be used in women of childbearing potential only when, in the judgment of the physician, the potential benefits outweigh the possible risks.

PRECAUTIONS

Chlorzoxazone should be used with caution in patients with known allergies or with a history of allergic reactions to drugs. If a sensitivity reaction occurs such as urticaria, redness, or itching of the skin, the drug should be stopped.

If any symptoms suggestive of liver dysfunction are observed, the drug should be discontinued

ADVERSE REACTIONS

Chlorzoxazone containing products are usually well tolerated. It is possible in rare instances that chlorzoxazone may have been associated with gastrointestinal bleeding. Drowsiness, dizziness, lightheadedness, malaise, or over-stimulation may be noted by an occasional patient. Rarely, allergic- type skin rashes, petechiae, or ecchymoses may develop during treatment. Angioneurotic edema or anaphylactic reactions are extremely rare. There is no evidence that the drug will cause renal damage. Rarely, a patient may note discoloration of the urine resulting from a phenolic metabolite of chlorzoxazone. This finding is of no known clinical significance.

To report SUSPECTED ADVERSE EVENTS, contact Novitium Pharma LLC at 1-855-204-1431 or FDA at 1-800- FDA-1088 or <http://www.fda.gov/> for voluntary reporting of adverse reactions.

OVERDOSAGE

Symptoms

Initially, gastrointestinal disturbances such as nausea, vomiting, or diarrhea together with drowsiness, dizziness, lightheadedness or headache may occur. Early in the course there may be malaise or sluggishness followed by marked loss of muscle tone, making voluntary movement impossible. The deep tendon reflexes may be decreased or absent. The sensorium remains intact, and there is no peripheral loss of sensation. Respiratory depression may occur with rapid, irregular respiration and intercostal and substernal retraction. The blood pressure is lowered, but shock has not been observed.

Treatment

Gastric lavage or induction of emesis should be carried out, followed by administration of activated charcoal. Thereafter, treatment is entirely supportive. If respirations are depressed, oxygen and artificial respiration should be employed and a patent airway assured by use of an oropharyngeal airway or endotracheal tube. Hypotension may be counteracted by use of dextran, plasma, concentrated albumin or a vasopressor agent such as norepinephrine. Cholinergic drugs or analeptic drugs are of no value and should not be used

DOSAGE & ADMINISTRATION

Usual Adult Dosage

One tablet three or four times daily. If adequate response is not obtained with this dose, it may be increased to one and one-half tablets (750 mg) three or four times daily. As improvement occurs dosage can usually be reduced.

HOW SUPPLIED

Chlorzoxazone Tablets, USP 500 mg for Oral administration are supplied as follows,

White to off-white capsule shaped tablets debossed with N085 on the bisected side:

NDC 70954-085-10
NDC 70954-085-20

100 Tablets
500 Tablets

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense contents with a child-resistant closure (as required) and in a tight container as defined in the USP/NF.

Manufactured by:
Novitium Pharma LLC
70 Lake Drive,
East Windsor, New Jersey-08520

Issued: 07/2020

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Chlorzoxazone Tablets, USP 500 mg - 100's Count

NDC 70954-085-10 100 Tablets

**Chlorzoxazone
Tablets, USP**

500 mg

novitium
pharma

Rx Only

Each Tablet Contains:
Chlorzoxazone, USP 500 mg

This is a bulk package. Dispense contents with a child-resistant closure (as required) and in a tight container as defined in the USP/NF.

Keep this and all medications out of the reach of children.

Usual Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Keep tightly closed.

Manufactured by:
Novitium Pharma LLC
70 Lake Drive, East Windsor
New Jersey 08520
Revised: 07/2020

LB4155-03

N 3 70954 085 10 2

NO VARNISH

Chlorzoxazone Tablets, USP 500 mg - 500's Count

NDC 70954-085-20

500 Tablets

Each Tablet Contains:
Chlorzoxazone, USP500 mg

Chlorzoxazone Tablets, USP

500 mg



Rx Only

This is a bulk package. Dispense contents with a child-resistant closure (as required) and in a tight container as defined in the USP/NF.

Keep this and all medications out of the reach of children.

Usual Dosage: See package insert for full prescribing information.

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Revised: 07/2020

LB4156-03



NO VARNISH

CHLORZOAZONE

chlorzoxazone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70954-085
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORZOAZONE (UNII: H0DE420U8G) (CHLORZOAZONE - UNII:H0DE420U8G)	CHLORZOAZONE	500 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	WHITE (White to off white)	Score	2 pieces
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Shape	CAPSULE (Capsule shaped tablet)		Size	17mm
Flavor			Imprint Code	N085
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70954-085-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2019	
2	NDC:70954-085-20	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA212254	09/12/2019		

Labeler - Novitium Pharma LLC (080301870)

Establishment

Name	Address	ID/FEI	Business Operations
Novitium Pharma LLC		080301870	MANUFACTURE(70954-085) , PACK(70954-085)

Revised: 10/2021

Novitium Pharma LLC