

CHLORZOXAZONE- chlorzoxazone tablet **Cameron Pharmaceuticals**

Chlorzoxazone Tablets, USP 375 mg and 750 mg

For Painful Musculoskeletal Conditions

PRESCRIBING INFORMATION

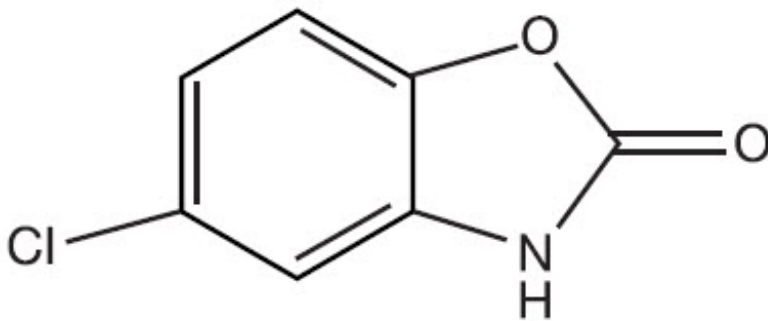
DESCRIPTION

Each 375 mg Chlorzoxazone tablet contains: Chlorzoxazone USP 375 mg.

Each 750 mg Chlorzoxazone tablet contains: Chlorzoxazone USP 750 mg.

Chemical Name: 5-Chloro-2-benzoxazolinone.

Structural Formula:



Molecular Formula: C₇H₄ClNO₂

Molecular Weight: 169.56

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.

Inactive ingredients: lactose monohydrate, pregelatinized starch, croscarmellose sodium, microcrystalline cellulose, docusate sodium, magnesium stearate, colloidal silicon dioxide, and sodium benzoate.

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 AND 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 judgement 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 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, light-headedness, malaise, or overstimulation 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.

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 intercostals 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 AND ADMINISTRATION

Usual Adult Dosage

Chlorzoxazone tablets USP 375 mg

One tablet three or four times daily. If adequate response is not obtained with this dose, the 375 mg tablets may be increased to two tablets (750 mg) three or four times daily. As improvement occurs dosage can usually be reduced.

Chlorzoxazone tablets USP 750 mg

1/3 tablet (250 mg) three or four times daily. Initial dosage for painful musculoskeletal conditions should be 2/3 tablet (500 mg) three or four times daily. If adequate response is not obtained with this dose, it may be increased to one tablet (750 mg) three or four times daily. As improvement occurs dosage can usually be reduced.

HOW SUPPLIED

Chlorzoxazone Tablets USP is available in the following strength and package size:

Chlorzoxazone Tablets USP **375 mg** for oral administration is supplied as follows:
A white to off white capsule shaped tablet, debossed "N084" on one side.

NDC 42494-425-10 Bottles of 100 Tablets

Chlorzoxazone Tablets USP **750 mg** for oral administration is supplied as follows:
A white to off white capsule shaped tablet, debossed "N86" on the trisected side and bisected on the other side.

NDC 42494-428-10 Bottles of 100 Tablets

Dispense in tight container as defined in the official compendium.

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

Manufactured for:

Cameron Pharmaceuticals
Louisville, KY 40245, USA

Manufactured by:

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

Issued: 08/2019

LB4154-01

PRINCIPAL DISPLAY PANEL - 750 mg Tablet Bottle Label

NDC 42494-428-10

100 Tablets

Chlorzoxazone
Tablets, USP

750 mg

CAMERON
PHARMACEUTICALS

Rx only

NDC 42494-428-10

100 Tablets

Each Tablet Contains:
Chlorzoxazone, USP750 mg

Usual Adult Dosage: For prescribing information, see accompanying product literature.

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

Dispense in a tight container as defined in the official compendium.

This is a bulk container.

Not Intended for household use.

Manufactured for:
Cameron Pharmaceuticals
Louisville, KY 40245, USA

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

Issued: 08/19

LB4153-01

Chlorzoxazone Tablets, USP

750 mg



Rx only



PRINCIPAL DISPLAY PANEL - 375 mg Tablet Bottle Label

NDC 42494-425-10

100 Tablets

Chlorzoxazone
Tablets, USP

375 mg

CAMERON
PHARMACEUTICALS

Rx only

NDC 42494-425-10

100 Tablets

Each Tablet Contains:
Chlorzoxazone, USP375 mg

Usual Adult Dosage: For prescribing information, see accompanying product literature.

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

Dispense in a tight container as defined in the official compendium.

This is a bulk container.

Not intended for household use.

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LB4152-01

Chlorzoxazone Tablets, USP

375 mg



Rx only



CHLORZOXAZONE

chlorzoxazone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42494-428
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Chlorzoxazone (UNII: H0DE420U8G) (Chlorzoxazone - UNII:H0DE420U8G)	Chlorzoxazone	750 mg

Inactive Ingredients

Ingredient Name	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND	Size	17mm
Flavor		Imprint Code	N86
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42494-428-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/27/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212254	11/27/2019	

CHLORZOXAZONE

chlorzoxazone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42494-425
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Chlorzoxazone (UNII: H0DE420U8G) (Chlorzoxazone - UNII:H0DE420U8G)	Chlorzoxazone	375 mg

Inactive Ingredients

Ingredient Name	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND	Size	17mm
Flavor		Imprint Code	N84
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42494-425-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/27/2019	
2	NDC:42494-425-08	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212254	11/27/2019	

Labeler - Cameron Pharmaceuticals (078371442)**Establishment**

Name	Address	ID/FEI	Business Operations
Novitium Pharma, LLC		080301870	MANUFACTURE(42494-428, 42494-425)

Revised: 4/2021

Cameron Pharmaceuticals