CHLORZOXAZONE- chlorzoxazone tablet, orally disintegrating
Belcher Pharmaceuticals LLC

CHLORZOXAZONE- Chlorzoxazone Tablet USP

Chlorzoxazone 250 mg

For Painful Musculoskeletal Conditions

DESCRIPTION

Each tablet contains: Chlorzoxazone*.....250 mg

* 5-Chloro-2-benzoxazolinone

Structural Formula:

Molecular Formula: $C_7H_4ClNO_2$

Molecular Weight: 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.

Inactive ingredients: anhydrous lactose, colloidal silicon dioxide, croscarmellose sodium, docusate sodium, magnesium stearate, microcrystalline cellulose, pregelatinized starch, 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 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

To report SUSPECTED ADVERSE REACTIONS, contact Belcher Pharmaceuticals, LLC at 727-471-0850 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

After extensive clinical use of chlorzoxazone-containing products, it is apparent that the product is well tolerated and seldom produces undesirable side effects. Occasional patients may develop gastrointestinal disturbances. It is possible in rare instances that chlorzoxazone may have been associated with gastrointestinal bleeding. Drowsiness,

dizziness, lightheadedness, 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 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 AND ADMINISTRATION

Usual Adult Dosage: One tablet (250 mg) three or four times daily. Initial dosage for painful musculoskeletal conditions should be two tablets (500 mg) three or four times daily. If adequate response is not obtained with this dose, it may be increased to three tablets (750 mg) three or four times daily. As improvement occurs dosage can usually be reduced.

HOW SUPPLIED

Chlorzoxazone tablets, USP, 250 mg are supplied as white, capsule-shaped tablets, debossed “BPL” on one side and “250” on the other side.

Bottles of 60 Tablets: NDC 62250-710-13

Dispense in tight container as defined in the USP.

Store at 20º to 25ºC (68º to 77ºF); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Manufacture by:

Belcher Pharmaceuticals LLC.

Largo, FL 33777

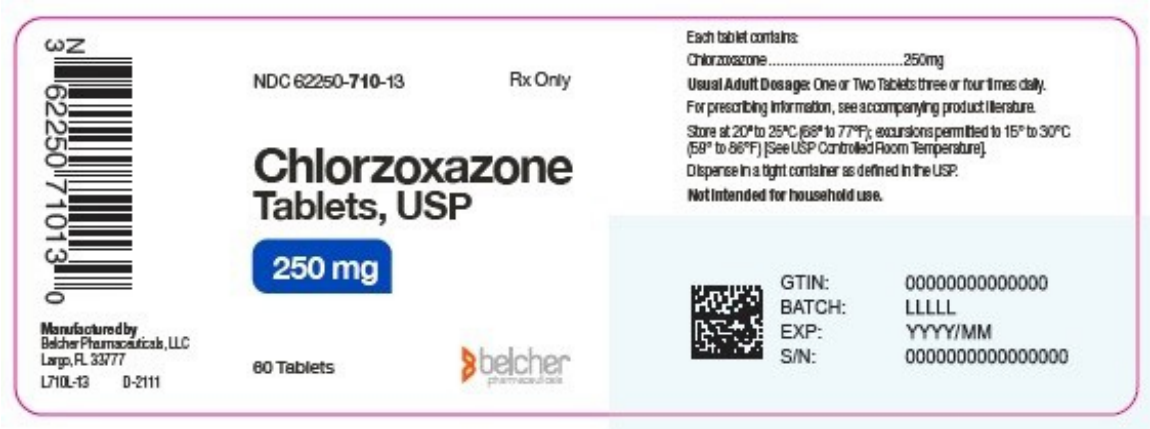
L75I

D-2111

Rev. 11/2021

PRINCIPAL DISPLAY PANEL

Rx only



CHLORZOXAZONE

chlorzoxazone tablet, orally disintegrating

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62250-710
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLORZOXAZONE (UNII: H0DE420U8G) (CHLORZOXAZONE - UNII:H0DE420U8G)	CHLORZOXAZONE	250 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
DOCUSATE SODIUM/SODIUM BENZOATE (UNII: 656HXR6YXN)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	white (A White to off white capsule shaped tablet debossed "BPL" on one side and "250" on the other side)	**Score**	no score
Shape	CAPSULE (capsule shaped tabletd)	**Size**	14mm

Flavor		**Imprint Code**	BPL;250
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62250-710-13	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/02/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215540	02/02/2023	

Labeler - Belcher Pharmaceuticals LLC (965082543)

Establishment

Name	Address	ID/FEI	Business Operations
Belcher Pharmaceuticals LLC		965082543	manufacture(62250-710) , analysis(62250-710)

Revised: 2/2023 Belcher Pharmaceuticals LLC