CHLORZOXAZONE- chlorzoxazone tablet
Par Pharmaceutical, Inc.

Rx only

For Painful Musculoskeletal Conditions

PRESCRIBING INFORMATION

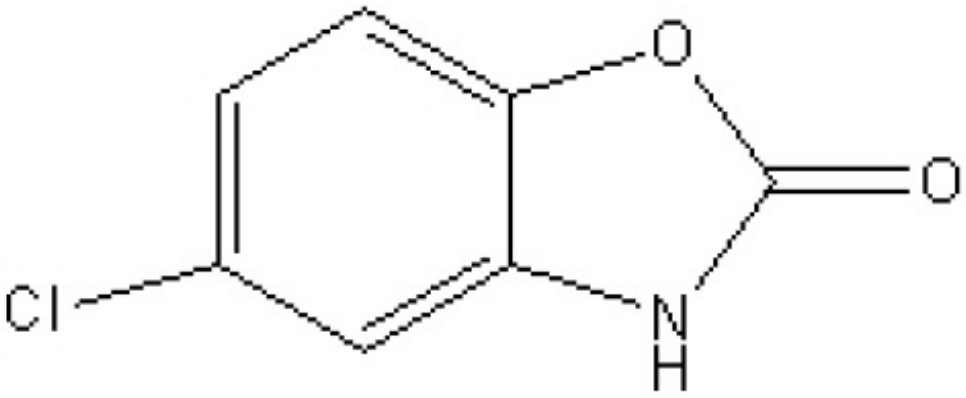
DESCRIPTION

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

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

Chemical Name: 5-Chloro-2-benzoxazolinone.

Structural Formula:



Molecular Formula: $C_7H_4ClNO_2$

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: anhydrous lactose, corn starch, croscarmellose sodium, DSS granular (docusate sodium 85% with sodium benzoate 15%), magnesium stearate, microcrystalline cellulose and pregelatinized starch (maize).

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 tablets are 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 tablets are 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 tablets 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, 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 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

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 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 are supplied as follows:

Chlorzoxazone tablets USP 375 mg are a white capsule shaped tablet, debossed “PAR” on the one side and “375” on another side. Free of physical defects.

Bottles of 100 tablets NDC 0254-2053-01

Chlorzoxazone tablets USP 750 mg are a white capsule shaped tablet, debossed “PAR” on the trisected side (functional scoring) and “750” on the bisected side (functional scoring).

Bottles of 100 tablets NDC 0254-2005-01

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].

To report SUSPECTED ADVERSE REACTIONS, contact Par Pharmaceutical at 1-800-828-9393 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Dist. by:

Par Pharmaceutical

Chestnut Ridge, NY 10977 U.S.A.

Mfg. by:

Par Formulations Private Limited,

9/215, Pudupakkam, Kelambakkam-603 103.

Made in India

Mfg. Lic. No.: TN00002121

OS2053-01-74-02

Revised: 10/2020

PACKAGE.LABEL.PRINCIPAL DISPLAY PANEL

Chlorzoxazone Tablets USP 375 mg - 100's Count Container Label

Chlorzoxazone Tablets USP 750 mg - 100's Count Container Label

CHLORZOXAZONE

chlorzoxazone tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0254-2005
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**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DOCUSATE SODIUM/SODIUM BENZOATE (UNII: 656HXR6YXN)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	white	**Score**	3 pieces
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	PAR;750
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0254-2005-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212743	11/04/2020	

CHLORZOXAZONE

chlorzoxazone tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0254-2053
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DOCUSATE SODIUM/SODIUM BENZOATE (UNII: 656HXR6YXN)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	white	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	PAR;375
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0254-2053-	100 in 1 BOTTLE; Type 0: Not a Combination	06/17/2021	

1	01	Product	06/17/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212743	06/17/2021	

Labeler - Par Pharmaceutical, Inc. (092733690)

Revised: 11/2020 Par Pharmaceutical, Inc.