

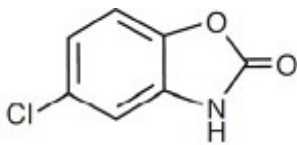
**CHLORZOXAZONE- chlorzoxazone tablet**  
**Actavis Pharma, Inc.**

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**Chlorzoxazone Tablets USP 500 mg**

**Rx Only**

**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, USP 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 USP contain the inactive ingredients docusate sodium, lactose (hydrous), magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium benzoate, and sodium starch glycolate.

**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**

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 Actavis at 1-800-272-5525 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 AND 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 are available as oblong, scored, white tablets debossed with **WPI** on one side and "39"- "68" on the other side and are packaged in bottles of 100 (NDC 0591-2520-01) and 500 (NDC 0591-2520-05).

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.

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

Manufactured In India By:  
Watson Pharma Private Limited  
Verna, Salcette Goa 403 722 INDIA

Distributed By:  
Actavis Pharma, Inc.

Parsippany, NJ 07054 USA

Rev. A 7/2019

## PRINCIPAL DISPLAY PANEL

NDC 0591-2520-01

Chlorzoxazone

Tablets USP

500 mg

Actavis

100 Tablets

Rx Only

The image shows the principal display panel for Chlorzoxazone Tablets USP 500 mg. The panel is white with a blue header and footer. The top left corner contains the NDC number 0591-2520-01. The top right corner features a blue box with '500 mg' in white. The center of the panel displays 'Chlorzoxazone Tablets USP' in large black font. Below this, there is a graphic of a white oval tablet with '39' and '68' on either side of a vertical score line. The Actavis logo is in the bottom left, and '100 Tablets Rx Only' is in the bottom right. The right side of the panel contains detailed text: 'Each Tablet Contains: Chlorzoxazone, USP ..... 500 mg', storage instructions, and manufacturer information. A barcode is located on the right side, with 'LOT/EXP. BELOW' printed vertically to its left and 'N 3 0591-2520-01 2' printed vertically to its right. The bottom right corner of the panel has the number '32076162-01'. A vertical orange bar on the far right is labeled 'Serialization Coding Area'.

## CHLORZOXAZONE

chlorzoxazone tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0591-2520
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL (oblong)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	WPI;39;68
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0591-2520-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/22/2011	
2	NDC:0591-2520-05	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/22/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA089859	08/22/2011	

**Labeler** - Actavis Pharma, Inc. (119723554)

Revised: 7/2019

Actavis Pharma, Inc.