CHLORZOXAZONE- chlorzoxazone tablet
Bryant Ranch Prepack

Chlorzoxazone Tablets, USP

For Painful Musculoskeletal Conditions

PRESCRIBING INFORMATION

DESCRIPTION

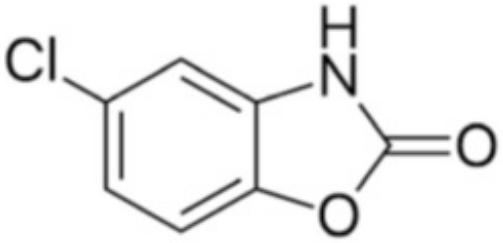
Each 375 mg chlorzoxazone tablet contains: Chlorzoxazone USP 375 mg.

Each 500 mg chlorzoxazone tablet contains: Chlorzoxazone USP 500 mg.

Each 750 mg chlorzoxazone tablet 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 USP 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:

375 mg contains colloidal silicon dioxide, corn starch, croscarmellose sodium, docusate sodium with sodium benzoate, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

500 mg contains D&C Red 27/Phloxine Aluminium lake, FD&C Yellow 6/Sunset Yellow FCF Aluminium lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 80, pregelatinized starch, sodium starch glycolate.

750 mg contains colloidal silicon dioxide, corn starch, croscarmellose sodium, docusate sodium with sodium benzoate, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

Meets USP dissolution test 5 for 500 mg.

FDA approved dissolution method differs from that of the USP for 375 mg and 750 mg.

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

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 Aurobindo Pharma USA, Inc. at 1-866-850-2876 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

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, 500 mg:

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.

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 are supplied as follows:

500 mg

A light orange to orange round shaped, flat hexagonal, beveled debossed with “N” on one side of break line and “500” on other side of break line and plain on other side.

NDC: 71335-2009-1: 20 TABLETs in a BOTTLE

NDC: 71335-2009-2: 30 TABLETs in a BOTTLE

NDC: 71335-2009-3: 40 TABLETs in a BOTTLE

NDC: 71335-2009-4: 90 TABLETs in a BOTTLE

NDC: 71335-2009-5: 60 TABLETs in a BOTTLE

NDC: 71335-2009-6: 100 TABLETs in a BOTTLE

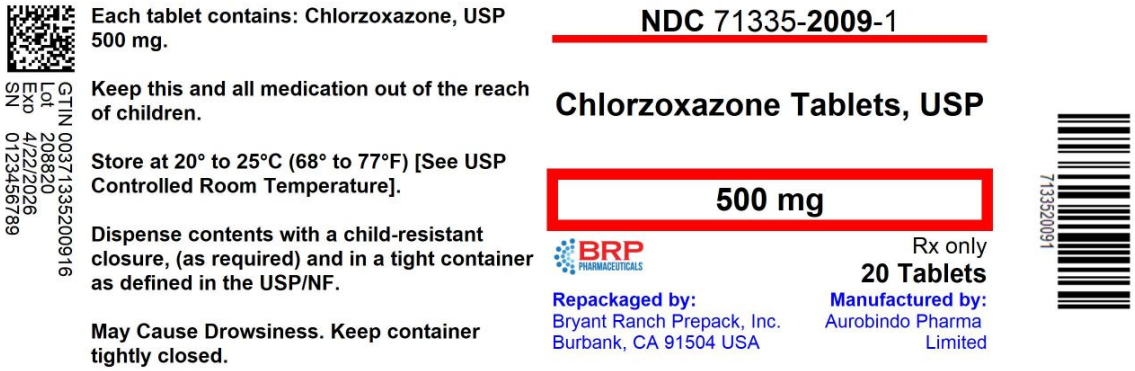
NDC: 71335-2009-7: 14 TABLETs in a BOTTLE

NDC: 71335-2009-8: 7 TABLETs in a BOTTLE

NDC: 71335-2009-9: 120 TABLETs in a BOTTLE

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

Chlorzoxazone 500mg Tablet



CHLORZOXAZONE

chlorzoxazone tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71335-2009(NDC:59651-306)
Route of Administration	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**
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	ORANGE (Light orange to orange)	**Score**	2 pieces
Shape	ROUND (flat, hexagonal)	**Size**	13mm
Flavor		**Imprint Code**	N;500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-2009-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	
2	NDC:71335-2009-2	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	
3	NDC:71335-2009-3	40 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	
4	NDC:71335-2009-4	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/03/2021	
5	NDC:71335-2009-5	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/22/2022	
6	NDC:71335-2009-6	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	
7	NDC:71335-2009-7	14 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	
8	NDC:71335-2009-8	7 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	
9	NDC:71335-2009-9	120 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA089853	08/03/2020	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-2009) , RELABEL(71335-2009)