

CHLORZOAZONE - chlorzoxazone tablet
Aurobindo Pharma Limited

Chlorzoxazone Tablets, USP

For Painful Musculoskeletal Conditions

PRESCRIBING INFORMATION

DESCRIPTION

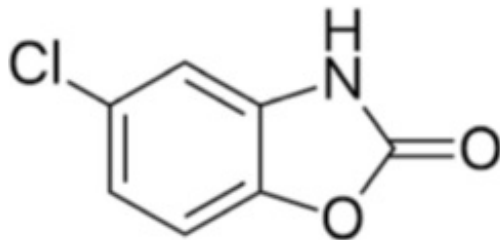
Each 375 mg chlorzoxazone tablet contains: Chlorzoxazone USP 375 mg.

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: C₇H₄ClNO₂

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:

375 mg

A white to off-white capsule shaped tablet debossed with "N" on one side and "375" on other side.

Bottles of 100

NDC 59651-305-01

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.

Bottles of 100 with child-resistant closure NDC 59651-306-01

Bottles of 500 NDC 59651-306-05

750 mg

A white to off-white capsule shaped tablet debossed with “N” on one side with trisect and “750” on other side with bisect.

Bottles of 100 NDC 59651- 307-01

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].

Distributed by:

Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Manufactured by:

Aurobindo Pharma Limited
Hyderabad-500 032, India

Revised: 09/2023

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 375 mg (100 Tablets Bottle)

NDC 59651-305-01

Rx only

Chlorzoxazone
Tablets, USP
375 mg

AUROBINDO 100 Tablets

NDC 59651-305-01

Rx only

**Chlorzoxazone
Tablets, USP**

375 mg

AUROBINDO 100 Tablets

Each tablet contains:
Chlorzoxazone USP 375 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.

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520
Made in India
Code: TS/DRUGS/16/2014

P1423161

* Over printing Zone

Coding Area
(45 x 15 mm)
Dotted lines not to be printed



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 500 mg (100 Tablets Bottle)

NDC 59651-306-01

Rx only

**Chlorzoxazone
Tablets, USP
500 mg**

AUROBINDO 100 Tablets

NDC 59651-306-01

Rx only

**Chlorzoxazone
Tablets, USP**

500 mg

AUROBINDO 100 Tablets

Each Tablet Contains:
Chlorzoxazone, USP..... 500 mg

This is a bulk package. 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.

Usual Dosage: See package insert for full prescribing information.

This package is child-resistant. Store at controlled room temperature 15°- 30°C (59°-86° F).

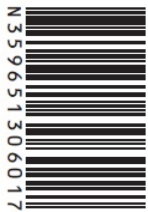
Keep tightly closed.

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520
Made in India
Code: TS/DRUGS/16/2014

P1423092

* Over Printing Zone

Coding Area
(45 x 20 mm)
Dotted lines not to be printed



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 750 mg (100 Tablets Bottle)

NDC 59651-307-01

Rx only

**Chlorzoxazone
Tablets, USP
750 mg**

AUROBINDO 100 Tablets

NDC 59651-307-01

Rx only

**Chlorzoxazone
Tablets, USP
750 mg**

AUROBINDO 100 Tablets

Not intended for household use.

Each tablet contains:
Chlorzoxazone USP 750 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.

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

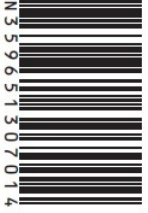
Made in India

Code: TS/DRUGS/16/2014

P1423163

* Over Printing Zone

Coding Area
(45 x 20 mm)
Dotted lines not to be printed



CHLORZOAZONE

chlorzoxazone tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:59651-305 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| CHLORZOAZONE (UNII: H0DE420U8G) (CHLORZOAZONE - UNII:H0DE420U8G) | | CHLORZOAZONE | 375 mg | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | | | | |
| DOCUSATE SODIUM/SODIUM BENZOATE (UNII: 656HXR6YXN) | | | | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | | |
| Product Characteristics | | | | |
| Color | WHITE (white to off white) | Score | no score | |
| Shape | CAPSULE | Size | 17mm | |
| Flavor | | Imprint Code | N;375 | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:59651-305-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 08/17/2023 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| ANDA | ANDA089853 | 08/17/2023 | | |

CHLORZOAZONE

chlorzoxazone tablet

| Product Information | | | |
|--|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:59651-306 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| CHLORZOAZONE (UNII: H0DE420U8G) (CHLORZOAZONE - UNII:H0DE420U8G) | | CHLORZOAZONE | 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:59651-306-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 08/03/2020 | |
| 2 | NDC:59651-306-05 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 08/03/2020 | |

Marketing Information

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

CHLORZOXAZONE

chlorzoxazone tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:59651-307 |
| 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 |
|--|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| DOCUSATE SODIUM/SODIUM BENZOATE (UNII: 656HXR6YXN) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |

Product Characteristics

| | | | |
|----------|----------------------------|--------------|----------|
| Color | WHITE (White to off white) | Score | 3 pieces |
| Shape | CAPSULE | Size | 20mm |
| Flavor | | Imprint Code | N;750 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59651-307-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 08/17/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA089853 | 08/17/2023 | |

Labeler - Aurobindo Pharma Limited (650082092)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|--|
| APL HEALTHCARE LIMITED | | 650844777 | ANALYSIS(59651-305, 59651-306, 59651-307) , MANUFACTURE(59651-305, 59651-306, 59651-307) |

Revised: 9/2023

Aurobindo Pharma Limited