CARISOPRODOL- carisoprodol tablet
Directrx

CARISOPRODOL

Carisoprodol is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults.

Limitation of Use
Carisoprodol should only be used for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use has not been established and because acute, painful musculoskeletal conditions are generally of short duration. [see DOSAGE AND ADMINISTRATION (2)].

The recommended dose of carisoprodol is 350 mg three times a day and at bedtime. The recommended maximum duration of carisoprodol use is up to two or three weeks.

350 mg Tablets: round, convex, white tablets, inscribed with 111 on one side and “O” on the other side.

Carisoprodol is contraindicated in patients with a history of acute intermittent porphyria or a hypersensitivity reaction to a carbamate such as meprobamate.

5.1 Sedation

Carisoprodol has sedative properties (in the low back pain trials, 13% to 17% of patients who received carisoprodol experienced sedation compared to 6% of patients who received placebo) [see ADVERSE REACTIONS (6.1)] and may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a motor vehicle or operating machinery. There have been post-marketing reports of motor vehicle accidents associated with the use of carisoprodol.

Since the sedative effects of carisoprodol and other CNS depressants (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants) may be additive, appropriate caution should be exercised with patients who take more than one of these CNS depressants simultaneously.

5.2 Abuse, Dependence, and Withdrawal

Carisoprodol, the active ingredient, has been subject to abuse, dependence, and withdrawal, misuse and criminal diversion. [see DRUG ABUSE AND DEPENDENCE (9.1, 9.2, 9.3)]. Abuse of carisoprodol poses a risk of overdosage which may lead to death, CNS and respiratory depression, hypotension, seizures and other disorders [see OVERDOSAGE (10)].

Post-marketing experience cases of carisoprodol abuse and dependence have been reported in patients with prolonged use and a history of drug abuse. Although most of these patients took other drugs of abuse, some patients solely abused carisoprodol. Withdrawal symptoms have been reported following abrupt cessation of carisoprodol after prolonged use. Reported withdrawal symptoms included insomnia, vomiting, abdominal cramps, headache, tremors, muscle twitching, ataxia, hallucinations, and psychosis. One of carisoprodol’s metabolites, meprobamate (a controlled substance), may also cause dependence [see CLINICAL PHARMACOLOGY (12.3)].

To reduce the risk of carisoprodol abuse assess the risk of abuse prior to prescribing. After prescribing, limit the length of treatment to three weeks for the relief of acute musculoskeletal discomfort, keep careful prescription records, monitor for signs of abuse and overdose, and educate patients and their families about abuse and on proper storage and disposal.

5.3 Seizures

There have been post-marketing reports of seizures in patients who received carisoprodol. Most of these cases have occurred in the setting of multiple drug overdoses (including drugs of abuse, illegal drugs, and alcohol) [see OVERDOSAGE (10)].

6.1 Clinical Studies Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect rates observed in practice.

The data described below are based on 1387 patients pooled from two double blind, randomized, multicenter, placebo controlled, one-week trials in adult patients with acute, mechanical, lower back pain [see CLINICAL STUDIES (14)]. In these studies, patients were treated with 250 mg of carisoprodol, 350 mg of carisoprodol, or placebo three times a day and at bedtime for seven days. The mean age was about 41 years old with 54% females and 46% males and 74 % Caucasian, 16 % Black, 9% Asian, and 2% other.

There were no deaths and there were no serious adverse reactions in these two trials. In these two studies, 2.7%, 2%, and 5.4%, of patients treated with placebo, 250 mg of carisoprodol, and 350 mg of carisoprodol, respectively, discontinued due to adverse events; and 0.5%, 0.5%, and 1.8% of patients treated with placebo, 250 mg of carisoprodol, and 350 mg of carisoprodol, respectively, discontinued due to central nervous system adverse reactions.

TABLE 1 displays adverse reactions reported with frequencies greater than 2% and more frequently than placebo in patients treated with carisoprodol in the two trials described above.

Table 1. Patients with Adverse Reactions in Controlled Studies
Adverse Reaction Placebo
(n=560)
n (%)

Carisoprodol 250 mg
(n=548)
n (%)

Carisoprodol 350 mg
(n=279)
n (%)
Drowsiness 31 (6)

73 (13)

47 (17)
Dizziness 11 (2) 43 (8) 19 (7)
Headache 11 (2) 26 (5) 9 (3)

6.2 Postmarketing Experience

The following events have been reported during postapproval use of carisoprodol. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Cardiovascular: Tachycardia, postural hypotension, and facial flushing [see OVERDOSAGE (10)].
Central Nervous System: Drowsiness, dizziness, vertigo, ataxia, tremor, agitation, irritability, headache, depressive reactions, syncope, insomnia, and seizures [see OVERDOSAGE (10)].
Gastrointestinal: Nausea, vomiting, and epigastric discomfort.
Hematologic: Leukopenia, pancytopenia

7.1 CNS Depressants

The sedative effects of carisoprodol and other CNS depressants (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants) may be additive. Therefore, caution should be exercised with patients who take more than one of these CNS depressants simultaneously. Concomitant use of carisoprodol and meprobamate, a metabolite of carisoprodol, is not recommended [see WARNINGS AND PRECAUTIONS (5.1)].

7.2 CYP2C19 Inhibitors and Inducers

Carisoprodol is metabolized in the liver by CYP2C19 to form meprobamate [see CLINICAL PHARMACOLOGY (12.3)]. Co-administration of CYP2C19 inhibitors, such as omeprazole or fluvoxamine, with carisoprodol could result in increased exposure of carisoprodol and decreased exposure of meprobamate. Co-administration of CYP2C19 inducers, such as rifampin or St. John’s Wort, with carisoprodol could result in decreased exposure of carisoprodol and increased exposure of meprobamate. Low dose aspirin also showed an induction effect on CYP2C19. The full pharmacological impact of these potential alterations of exposures in terms of either efficacy or safety of carisoprodol is unknown.

8.1 Pregnancy

Risk Summary
Data over many decades of carisoprodol use in pregnancy have not identified a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Data on meprobamate, the primary metabolite of carisoprodol, also do not show a consistent association between maternal use of meprobamate and an increased risk of major birth defects (see DATA).

In a published animal reproduction study, pregnant mice administered carisoprodol orally at 2.6 and 4.1-times the maximum recommended human dose ([MRHD] of 1400 mg per day [350 mg QID] based on body surface area [BSA] comparison) from gestation through weaning resulted in reduced fetal weights, postnatal weight gain, and postnatal survival (see DATA)..

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and

15 to 20%, respectively.

Data
Human Data
Retrospective case-control and cohort studies of meprobamate use during the first trimester of pregnancy have not consistently identified an increased risk or pattern of major birth defects. For children exposed to meprobamate in-utero, one study found no adverse effect on mental or motor development or IQ scores.

Animal Data
Embryofetal development studies in animals have not been completed.

In a published pre- and post-natal development animal study, pregnant mice administered carisoprodol orally at 300, 750, or 1200 mg/kg/day (approximately 1-, 2.6-, and 4.1-times the MRHD based on BSA comparison) from 7-days prior to gestation through birth and from lactation through weaning resulted in reduced fetal weights, postnatal weight gain, and postnatal survival at 2.6- and 4.1-times the MRHD.

8.2 Lactation

Risk Summary
Data from published literature report that carisoprodol and its metabolite, meprobamate, are present in breastmilk. There are no data on the effect of carisoprodol on milk production. There is one report of sedation in an infant who was breastfed by a mother taking carisoprodol (see CLINICAL CONSIDERATIONS). Because there have been no consistent reports of adverse events in breastfed infants over decades of use, the developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for carisoprodol and any potential adverse effects on the breastfed infant from carisoprodol or from the underlying maternal condition.

Clinical Considerations
Infants exposed to carisoprodol through breast milk should be monitored for sedation.

8.4 Pediatric Use

The efficacy, safety, and pharmacokinetics of carisoprodol in pediatric patients less than 16 years of age have not been established.

8.5 Geriatric Use

The efficacy, safety, and pharmacokinetics of carisoprodol in patients over 65 years old have not been established.

8.6 Renal Impairment

The safety and pharmacokinetics of carisoprodol in patients with renal impairment have not been evaluated. Since carisoprodol is excreted by the kidney, caution should be exercised if carisoprodol is administered to patients with impaired renal function. Carisoprodol is dialyzable by hemodialysis and peritoneal dialysis.

8.7 Hepatic Impairment

The safety and pharmacokinetics of carisoprodol in patients with hepatic impairment have not been evaluated. Since carisoprodol is metabolized in the liver, caution should be exercised if carisoprodol is administered to patients with impaired hepatic function.

8.8 Patients with Reduced CYP2C19 Activity

Patients with reduced CYP2C19 activity have higher exposure to carisoprodol. Therefore, caution should be exercised in administration of carisoprodol to these patients. [see CLINICAL PHARMACOLOGY (12.3)].

9.1 Controlled Substance

Carisoprodol is a Schedule IV controlled substance. Carisoprodol has been subject to abuse, misuse, and criminal diversion for nontherapeutic use [see WARNINGS AND PRECAUTIONS (5.2)].

9.2 Abuse

Abuse of carisoprodol poses a risk of overdosage which may lead to death, CNS and respiratory depression, hypotension, seizures and other disorders [see WARNINGS AND PRECAUTIONS (5.2) and OVERDOSAGE (10)]. Patients at high risk of carisoprodol abuse may include those with prolonged use of carisoprodol, with a history of drug abuse, or those who use carisoprodol in combination with other abused drugs.

Prescription drug abuse is the intentional non-therapeutic use of a drug, even once, for its rewarding psychological effects. Drug addiction, which develops after repeated drug abuse, is characterized by a strong desire to take a drug despite harmful consequences, difficulty in controlling its use, giving a higher priority to drug use than to obligations, increased tolerance, and sometimes physical withdrawal. Drug abuse and drug addiction are separate and distinct from physical dependence and tolerance (for example, abuse or addiction may not be accompanied by tolerance or physical dependence) [see DRUG ABUSE AND DEPENDENCE (9.3)].

9.3 Dependence

Tolerance is when a patient’s reaction to a specific dosage and concentration is progressively reduced in the absence of disease progression, requiring an increase in the dosage to maintain the same. Physical dependence is characterized by withdrawal symptoms after abrupt discontinuation or a significant dose reduction of a drug. Both tolerance and physical dependence have been reported with the prolonged use of carisoprodol. Reported withdrawal symptoms with carisoprodol include insomnia, vomiting, abdominal cramps, headache, tremors, muscle twitching, anxiety, ataxia, hallucinations, and psychosis. Instruct patients taking large doses of carisoprodol or those taking the drug for a prolonged time to not abruptly stop carisoprodol [see WARNINGS AND PRECAUTIONS (5.2)].

Clinical Presentation
Overdosage of carisoprodol commonly produces CNS depression. Death, coma, respiratory depression, hypotension, seizures, delirium, hallucinations, dystonic reactions, nystagmus, blurred vision, mydriasis, euphoria, muscular incoordination, rigidity, and/or headache have been reported with carisoprodol overdosage. Serotonin syndrome has been reported with carisoprodol intoxication. Many of the carisoprodol overdoses have occurred in the setting of multiple drug overdoses (including drugs of abuse, illegal drugs, and alcohol). The effects of an overdose of carisoprodol and other CNS depressants (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants) can be additive even when one of the drugs has been taken in the recommended dosage. Fatal accidental and non-accidental overdoses of carisoprodol have been reported alone or in combination with CNS depressants.

Treatment of Overdosage

Basic life support measures should be instituted as dictated by the clinical presentation of the carisoprodol overdose. Vomiting should not be induced because of the risk of CNS and respiratory depression, and subsequent aspiration. Circulatory support should be administered with volume infusion and vasopressor agents if needed. Seizures should be treated with intravenous benzodiazepines and the reoccurrence of seizures may be treated with phenobarbital. In cases of severe CNS depression, airway protective reflexes may be compromised and tracheal intubation should be considered for airway protection and respiratory support.

For decontamination in cases of severe toxicity, activated charcoal should be considered in a hospital setting in patients with large overdoses who present early and are not demonstrating CNS depression and can protect their airway.

For more information on the management of an overdose of carisoprodol, contact a Poison Control Center.

Carisoprodol tablets are available as 350 mg round, white tablets. Carisoprodol is a white, crystalline powder, having a mild, characteristic odor and a bitter taste. It is slightly soluble in water; freely soluble in alcohol, in chloroform, and in acetone; and its solubility is practically independent of pH. Carisoprodol is present as a racemic mixture. Chemically, carisoprodol is (±)-2-Methyl-2-propyl-1,3-propanediol carbamate isopropylcarbamate and the molecular formula is $C_{12}H_{24}N_2O_4$, with a molecular weight of 260.33. The structural formula is:

[Structural Formula]

Other ingredients in the carisoprodol drug product include hydroxypropyl methylcellulose, lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, stearic acid and talc.

350 mg Tablets: round, convex, white tablets, inscribed with 111 on one side and “O” on the other side; available in bottles of 100 (NDC 69584-111-10), bottles of 500 (NDC 69584-111-50) and bottles of 1000 (NDC 69584-111-90).

Storage
Store at controlled room temperature 20° - 25°C (68° - 77°F).

Patients should be advised to contact their physician if they experience any adverse reactions to carisoprodol.

Sedation
Advise patients that carisoprodol may cause drowsiness and/or dizziness, and has been associated with motor vehicle accidents. Patients should be advised to avoid taking carisoprodol before engaging in potentially hazardous activities such as driving a motor vehicle or operating machinery [see WARNINGS AND PRECAUTIONS (5.1)].

Avoidance of Alcohol and Other CNS Depressants
Advise patients to avoid alcoholic beverages while taking carisoprodol and to check with their doctor before taking other CNS depressants such as benzodiazepines, opioids, tricyclic antidepressants, sedating antihistamines, or other sedatives [see WARNINGS AND PRECAUTIONS (5.1)].

Carisoprodol Should Only Be Used for Short-Term Treatment
Advise patients that treatment with carisoprodol should be limited to acute use (up to two or three weeks) for the relief of acute, musculoskeletal discomfort. In the post-

marketing experience with carisoprodol, cases of dependence, withdrawal, and abuse have been reported with prolonged use. If the musculoskeletal symptoms still persist, patients should contact their healthcare provider for further evaluation.

Lactation
Advise nursing mothers using carisoprodol to monitor neonates for signs of sedation [see USE IN SPECIFIC POPULATIONS (8.2)].

Oxford Pharmaceuticals, LLC
Birmingham, AL 35211
8200005
09/2019 REV00
© 2019 Oxford Pharmaceuticals, LLC

Patients should be advised to contact their physician if they experience any adverse reactions to carisoprodol.

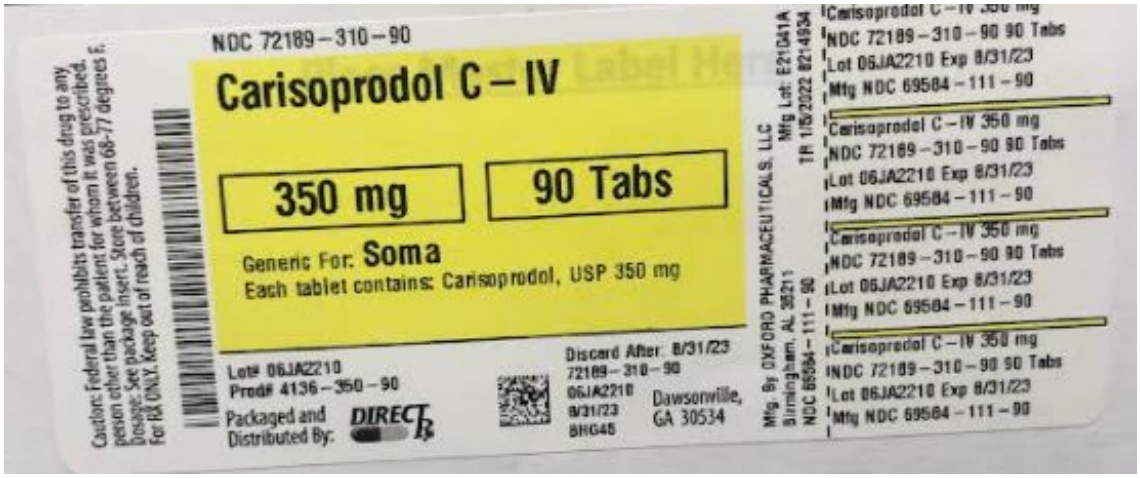
Sedation
Advise patients that carisoprodol may cause drowsiness and/or dizziness, and has been associated with motor vehicle accidents. Patients should be advised to avoid taking carisoprodol before engaging in potentially hazardous activities such as driving a motor vehicle or operating machinery [see WARNINGS AND PRECAUTIONS (5.1)].

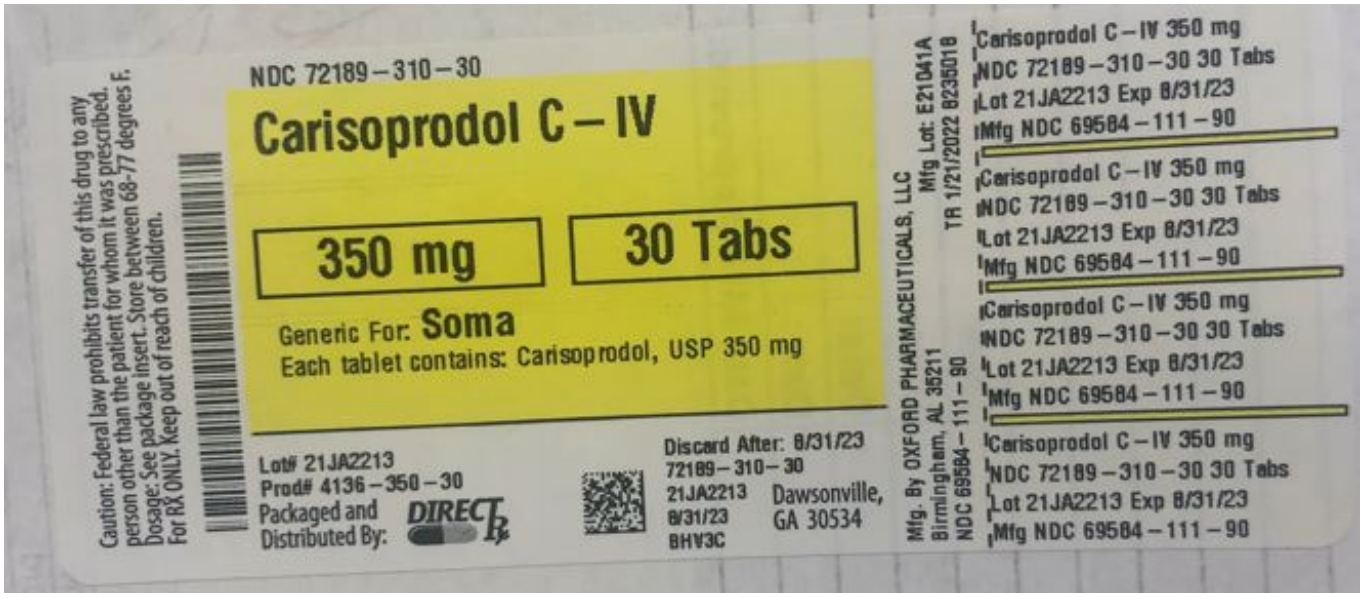
Avoidance of Alcohol and Other CNS Depressants
Advise patients to avoid alcoholic beverages while taking carisoprodol and to check with their doctor before taking other CNS depressants such as benzodiazepines, opioids, tricyclic antidepressants, sedating antihistamines, or other sedatives [see WARNINGS AND PRECAUTIONS (5.1)].

Carisoprodol Should Only Be Used for Short-Term Treatment
Advise patients that treatment with carisoprodol should be limited to acute use (up to two or three weeks) for the relief of acute, musculoskeletal discomfort. In the post-marketing experience with carisoprodol, cases of dependence, withdrawal, and abuse have been reported with prolonged use. If the musculoskeletal symptoms still persist, patients should contact their healthcare provider for further evaluation.

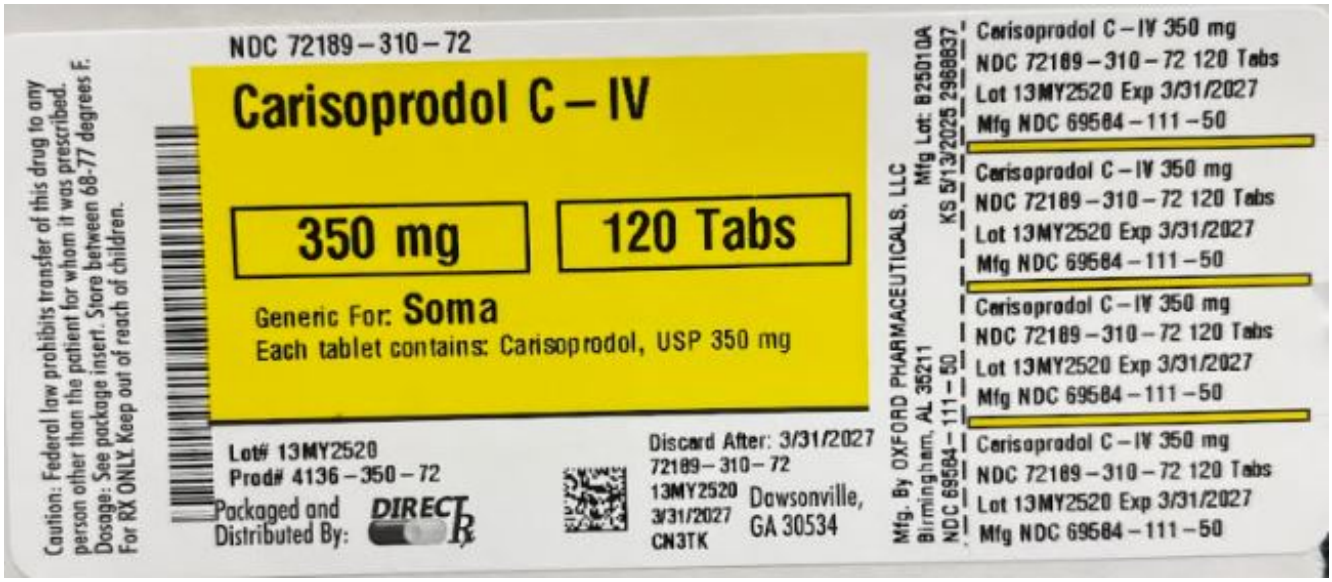
Lactation
Advise nursing mothers using carisoprodol to monitor neonates for signs of sedation [see USE IN SPECIFIC POPULATIONS (8.2)].

Oxford Pharmaceuticals, LLC
Birmingham, AL 35211
8200005
09/2019 REV00
© 2019 Oxford Pharmaceuticals, LLC


NDC 72189-310-90
Carisoprodol C-IV
350 mg
90 Tabs
Generic For: Soma
Each tablet contains: Carisoprodol, USP 350 mg
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed. Dosage: See package insert. Store between 68-77 degrees F. For RX ONLY. Keep out of reach of children.
Lot# 06JA2210
Prod# 4136-350-90
Packaged and Distributed By: DIRECT Rx
Discard After: 8/31/23
72189-310-90
06JA2210
8/31/23
BHG45
Dawsonville, GA 30534
Mfg. By OXFORD PHARMACEUTICALS, LLC
Birmingham, AL 35211
NDC 69584-111-90
Mfg Lot: E21041A
TR 1/5/2022 8214934
Carisoprodol C-IV 350 mg
NDC 72189-310-90 90 Tabs
Lot 06JA2210 Exp 8/31/23
Mfg NDC 69584-111-90


NDC 72189-310-30
Carisoprodol C-IV
350 mg
30 Tabs
Generic For: Soma
Each tablet contains: Carisoprodol, USP 350 mg
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed. Dosage: See package insert. Store between 68-77 degrees F. For RX ONLY. Keep out of reach of children.
Lot# 21JA2213
Prod# 4136-350-30
Packaged and Distributed By: DIRECT Rx
Discard After: 8/31/23
72189-310-30
21JA2213
8/31/23
BHV3C
Dawsonville, GA 30534
Mfg. By OXFORD PHARMACEUTICALS, LLC
Birmingham, AL 35211
NDC 69584-111-90
Mfg Lot: E21041A
TR 1/21/2022 8235018
Carisoprodol C-IV 350 mg
NDC 72189-310-30 30 Tabs
Lot 21JA2213 Exp 8/31/23
Mfg NDC 69584-111-90


NDC 72189-310-60
Carisoprodol C-IV
350 mg
60 Tabs
Generic For: Soma
Each tablet contains: Carisoprodol, USP 350 mg
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed. Dosage: See package insert. Store between 68-77 degrees F. For RX ONLY. Keep out of reach of children.
Lot# 27JA2218
Prod# 4136-350-60
Packaged and Distributed By: DIRECT Rx
Discard After: 8/31/23
72189-310-60
27JA2218
8/31/23
Dawsonville, GA 30534
Mfg. By OXFORD PHARMACEUTICALS, LLC
Birmingham, AL 35211
NDC 69584-111-90
Mfg Lot: E21041A
TR 1/27/2022 8241178
Carisoprodol C-IV 350 mg
NDC 72189-310-60 60 Tabs
Lot 27JA2218 Exp 8/31/23
Mfg NDC 69584-111-90



CARISOPRODOL

carisoprodol tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72189-310(NDC:69584-111)
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CARISOPRODOL (UNII: 21925K482H) (CARISOPRODOL - UNII:21925K482H)	CARISOPRODOL	350 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSE 2910 (50 MPA.S) (UNII: 1IVH67816N)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	111;O
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-310-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2022	
2	NDC:72189-310-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2022	
3	NDC:72189-310-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2022	
4	NDC:72189-310-72	120 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040188	01/17/2022	

Labeler - Directrx (079254320)

Registrant - Directrx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Directrx		079254320	relabel(72189-310)

Revised: 3/2026 Directrx