

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SOMA safely and effectively. See full prescribing information for SOMA.

SOMA (carisoprodol) Tablets for Oral use
Initial U.S. Approval: 1959

-----**RECENT MAJOR CHANGES**-----

Indications and Usage (1) 9/2007
Dosage and Administration (2) 9/2007

-----**INDICATIONS AND USAGE**-----

SOMA is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions. (1)

Important Limitations:

- Should only be used for acute treatment periods up to two or three weeks (1)
- Not recommended in pediatric patients less than 16 years of age (8.4)

-----**DOSAGE AND ADMINISTRATION**-----

- Recommended dose is 250 mg to 350 mg three times a day and at bedtime. (2)

-----**DOSAGE FORMS AND STRENGTHS**-----

Tablets: 250 mg, 350 mg (3)

-----**CONTRAINDICATIONS**-----

- Acute intermittent porphyria (4)
- Hypersensitivity reactions to a carbamate such as meprobamate (4)

-----**WARNINGS AND PRECAUTIONS**-----

- Due to sedative properties, may impair ability to perform hazardous tasks such as driving or operating machinery (5.1)
- Additive sedative effects when used with other CNS depressants including alcohol (5.1)
- Cases of Drug Dependence, Withdrawal, and Abuse (5.2)
- Seizures (5.3)

-----**ADVERSE REACTIONS**-----

Most common adverse reactions (incidence > 2%) are drowsiness, dizziness, and headache (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact MedPointe Pharmaceuticals at 1-800-526-3840 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

-----**DRUG INTERACTIONS**-----

- CNS depressants (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants) - additive sedative effects (5.1 and 7.1)

See 17 for **PATIENT COUNSELING INFORMATION**
revised 9/2007

FULL PRESCRIBING INFORMATION: CONTENTS*

1	INDICATIONS AND USAGE	9	DRUG ABUSE AND DEPENDENCE
2	DOSAGE AND ADMINISTRATION	10	OVERDOSAGE
3	DOSAGE FORMS AND STRENGTHS	11	DESCRIPTION
4	CONTRAINDICATIONS	12	CLINICAL PHARMACOLOGY
5	WARNINGS AND PRECAUTIONS	12.1	Mechanism of Action
5.1	Sedation	12.2	Pharmacodynamics
5.2	Drug Dependence, Withdrawal, and Abuse	12.3	Pharmacokinetics
5.3	Seizures	13	NONCLINICAL TOXICOLOGY
6	ADVERSE REACTIONS	13.1	Carcinogenesis, Mutagenesis, Impairment of Fertility
6.1	Clinical Studies Experience	14	CLINICAL STUDIES
6.2	Postmarketing Experience	16	HOW SUPPLIED/STORAGE AND HANDLING
7	DRUG INTERACTIONS	17	PATIENT COUNSELING INFORMATION
7.1	CNS Depressants	17.1	Sedation
7.2	CYP2C19 Inhibitors and Inducers	17.2	Avoidance of Alcohol and Other CNS Depressants
8	USE IN SPECIFIC POPULATIONS	17.3	SOMA Should Only be Be Used for Short-Term Treatment
8.1	Pregnancy		
8.2	Labor and Delivery		
8.3	Nursing Mothers		
8.4	Pediatric Use		
8.5	Geriatric Use		
8.6	Renal Impairment		
8.7	Hepatic Impairment		
8.8	Patients with Reduced CYP2C19 Activity		

* Sections or subsections omitted from the full prescribing information are not listed

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57

FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

1 SOMA is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults.
2 SOMA should **only** be used for short periods (up to two or three weeks) because adequate evidence of effectiveness for more
3 prolonged use has not been established and because acute, painful musculoskeletal conditions are generally of short duration- [see
4 *Dosage and Administration (2)*].

DOSAGE AND ADMINISTRATION

5 The recommended dose of SOMA is 250 mg to 350 mg three times a day and at bedtime. The recommended maximum
6 duration of SOMA use is up to two or three weeks.

DOSAGE FORMS AND STRENGTHS

7 250 mg Tablets: round, convex, white tablets, inscribed with SOMA 250
8 350 mg Tablets: round, convex, white tablets, inscribed with SOMA 350

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

5.1 Sedation

11 SOMA may have sedative properties (in the low back pain trials, 13% to 17% of patients who received SOMA experienced
12 sedation compared to 6% of patients who received placebo) [see *ADVERSE REACTIONS (6.1)*] and may impair the mental and/or
13 physical abilities required for the performance of potentially hazardous tasks such as driving a motor vehicle or operating machinery.

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

5.2 Drug Dependence, Withdrawal, and Abuse

17 In the postmarketing experience with SOMA, cases of dependence, withdrawal, and abuse have been reported with prolonged
18 use. Most cases of dependence, withdrawal, and abuse occurred in patients who have had a history of addiction or who used SOMA in
19 combination with other drugs with abuse potential. Withdrawal symptoms have been reported following abrupt cessation after
20 prolonged use. To reduce the chance of SOMA dependence, withdrawal, or abuse, SOMA should be used with caution in addiction-
21 prone patients and in patients taking other CNS depressants including alcohol, and SOMA should be not be used more than two to
22 three weeks for the relief of acute musculoskeletal discomfort.

23 One of the metabolites of SOMA, meprobamate (a controlled substance), may cause dependence [see *Clinical Pharmacology*
24 (12.3)].

5.3 Seizures

25 There have been postmarketing reports of seizures in patients who received SOMA. Most of these cases have occurred in the
26 setting of multiple drug overdoses (including drugs of abuse, illegal drugs, and alcohol) [see *Overdosage (10)*].

ADVERSE REACTIONS

6.1 Clinical Studies Experience

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

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

33 There were no deaths and there were no serious adverse reactions in these two trials. In these two studies, 2.7%, 2%, and
34 5.4%, of patients treated with placebo, 250 mg of SOMA, and 350 mg of SOMA, respectively, discontinued due to adverse events;
35 and 0.5%, 0.5%, and 1.8% of patients treated with placebo, 250 mg of SOMA, and 350 mg of SOMA, respectively, discontinued due
36 to central nervous system adverse reactions.

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

39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57

Adverse Reaction	Placebo (n=560) n (%)	SOMA 250 mg (n=548) n (%)	SOMA 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

58 The following events have been reported during postapproval use of SOMA. Because these reactions are reported voluntarily
59 from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to
60 drug exposure.
61
62

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

69 7 **DRUG INTERACTIONS**

70 7.1 **CNS Depressants**

71 The sedative effects of SOMA and other CNS depressants (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants)
72 may be additive. Therefore, caution should be exercised with patients who take more than one of these CNS depressants
73 simultaneously. Concomitant use of SOMA and meprobamate, a metabolite of SOMA, is not recommended [*see Warnings and*
74 *Precautions (5.1)*].

75 7.2 **CYP2C19 Inhibitors and Inducers**

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

83 8 **USE IN SPECIFIC POPULATION**

84 8.1 **Pregnancy: Pregnancy Category C.**

85 There are no data on the use of SOMA during human pregnancy. Animal studies indicate that carisoprodol crosses the
86 placenta and results in adverse effects on fetal growth and postnatal survival. The primary metabolite of carisoprodol, meprobamate, is
87 an approved anxiolytic. Retrospective, post-marketing studies do not show a consistent association between maternal use of
88 meprobamate and an increased risk for particular congenital malformations.

89 *Teratogenic effects* Animal studies have not adequately evaluated the teratogenic effects of carisoprodol. There was no
90 increase in the incidence of congenital malformations noted in reproductive studies in rats, rabbits, and mice treated with
91 meprobamate. Retrospective, post-marketing studies of meprobamate during human pregnancy were equivocal for demonstrating an
92 increased risk of congenital malformations following first trimester exposure. Across studies that indicated an increased risk, the types
93 of malformations were inconsistent.

94 *Nonteratogenic effects* In animal studies, carisoprodol reduced fetal weights, postnatal weight gain, and postnatal survival at
95 maternal doses equivalent to 1-1.5 times the human dose (based on a mg/m²-body surface area comparison). Rats exposed to
96 meprobamate in-utero showed behavioral alterations that persisted into adulthood. For children exposed to
97 meprobamate in-utero, one study found no adverse effects on mental or motor development or IQ scores. SOMA should be used
98 during pregnancy only if the potential benefit justifies the risk to the fetus.

99 8.2 **Labor and Delivery**

100 There is no information about the effects of SOMA on the mother and the fetus during labor and delivery.

101 8.3 **Nursing Mothers**

102 Very limited data in humans show that SOMA is present in breast milk and may reach concentrations two to four times the
103 maternal plasma concentrations. In one case report, a breast-fed infant received about 4-6% of the maternal daily dose through breast
104 milk and experienced no adverse effects. However, milk production was inadequate and the baby was supplemented with formula. In
105 lactation studies in mice, female pup survival and pup weight at weaning were decreased. This information suggests that maternal use
106 of SOMA may lead to reduced or less effective infant feeding (due to sedation) and/or decreased milk production. Caution should be
107 exercised when SOMA is administered to a nursing woman.

108 8.4 **Pediatric Use**

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

110 8.5 **Geriatric Use**

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

112 8.6 **Renal Impairment**

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

116 8.7 **Hepatic Impairment**

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

119 8.8 **Patients with Reduced CYP2C19 Activity**

120 Patients with reduced CYP2C19 activity have higher exposure to carisoprodol. Therefore, caution should be exercised in
121 administration of SOMA to these patients [*see Clinical Pharmacology (12.3)*].

123 9 **DRUG ABUSE AND DEPENDENCE**

124 [*see Warnings and Precautions (5.2)*]

126 10 **OVERDOSAGE**

127 Overdosage of SOMA commonly produces CNS depression. Death, coma, respiratory depression, hypotension, seizures,
128 delirium, hallucinations, dystonic reactions, nystagmus, blurred vision, mydriasis, euphoria, muscular incoordination, rigidity, and/or
129 headache have been reported with SOMA overdosage. Many of the SOMA overdoses have occurred in the setting of multiple drug
130 overdoses (including drugs of abuse, illegal drugs, and alcohol). The effects of an overdose of SOMA and other CNS depressants
131 (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants) can be additive even when one of the drugs has been taken in the

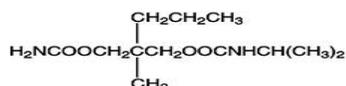
recommended dosage. Fatal accidental and non-accidental overdoses of SOMA have been reported alone or in combination with CNS depressants.

Treatment of Overdosage: Basic life support measures should be instituted as dictated by the clinical presentation of the SOMA overdose. Induced emesis is not recommended due to the risk of CNS and respiratory depression, which may increase the risk of aspiration pneumonia. Gastric lavage should be considered soon after ingestion (within one hour). 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.

The following types of treatment have been used successfully with an overdose of meprobamate, a metabolite of SOMA: activated charcoal (oral or via nasogastric tube), forced diuresis, peritoneal dialysis, and hemodialysis (carisoprodol is also dialyzable). Careful monitoring of urinary output is necessary and overhydration should be avoided. Observe for possible relapse due to incomplete gastric emptying and delayed absorption. For more information on the management of an overdose of SOMA, **contact a Poison Control Center.**

11 DESCRIPTION

SOMA (carisoprodol) Tablets are available as 250 mg and 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 N-isopropyl-2-methyl-2-propyl-1,3-propanediol dicarbamate and the molecular formula is $C_{12}H_{24}N_2O_4$, with a molecular weight of 260.33. The structural formula is:



Other ingredients in the SOMA drug product include alginic acid, magnesium stearate, potassium sorbate, starch, and tribasic calcium phosphate.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of carisoprodol in relieving discomfort associated with acute painful musculoskeletal conditions has not been clearly identified.

In animal studies, muscle relaxation induced by carisoprodol is associated with altered interneuronal activity in the spinal cord and in the descending reticular formation of the brain.

12.2 Pharmacodynamics

Carisoprodol is a centrally acting skeletal muscle relaxant that does not directly relax skeletal muscles.

A metabolite of carisoprodol, meprobamate, has anxiolytic and sedative properties. The degree to which these properties of meprobamate contribute to the safety and efficacy of SOMA is unknown.

12.3 Pharmacokinetics

The pharmacokinetics of carisoprodol and its metabolite meprobamate were studied in a crossover study of 24 healthy subjects (12 male and 12 female) who received single doses of 250 mg and 350 mg SOMA (see Table 2). The exposure of carisoprodol and meprobamate was dose proportional between the 250 mg and 350 mg doses. The C_{max} of meprobamate was $2.5 \pm 0.5 \mu\text{g/mL}$ (mean \pm SD) after administration of a single 350 mg dose of SOMA, which is approximately 30% of the C_{max} of meprobamate (approximately $8 \mu\text{g/mL}$) after administration of a single 400 mg dose of meprobamate.

	250 mg SOMA	350 mg SOMA
Carisoprodol		
C_{max} ($\mu\text{g/mL}$)	1.2 ± 0.5	1.8 ± 1.0
AUC_{inf} ($\mu\text{g}^2\text{hr/mL}$)	4.5 ± 3.1	7.0 ± 5.0
T_{max} (hr)	1.5 ± 0.8	1.7 ± 0.8
$T_{1/2}$ (hr)	1.7 ± 0.5	2.0 ± 0.5
Meprobamate		
C_{max} ($\mu\text{g/mL}$)	1.8 ± 0.3	2.5 ± 0.5
AUC_{inf} ($\mu\text{g}^2\text{hr/mL}$)	32 ± 6.2	46 ± 9.0
T_{max} (hr)	3.6 ± 1.7	4.5 ± 1.9
$T_{1/2}$ (hr)	9.7 ± 1.7	9.6 ± 1.5

Absorption: Absolute bioavailability of carisoprodol has not been determined. The mean time to peak plasma concentrations (T_{max}) of carisoprodol was approximately 1.5 to 2 hours. Co-administration of a high-fat meal with SOMA (350 mg tablet) had no effect on the pharmacokinetics of carisoprodol. Therefore, SOMA may be administered with or without food.

Metabolism: The major pathway of carisoprodol metabolism is via the liver by cytochrome enzyme CYP2C19 to form meprobamate. This enzyme exhibits genetic polymorphism (see Patients with Reduced CYP2C19 Activity below).

Elimination: Carisoprodol is eliminated by both renal and non-renal routes with a terminal elimination half-life of approximately 2 hours. The half-life of meprobamate is approximately 10 hours.

Gender: Exposure of carisoprodol is higher in female than in male subjects (approximately 30-50% on a weight adjusted basis). Overall exposure of meprobamate is comparable between female and male subjects.

183 *Patients with Reduced CYP2C19 Activity* SOMA should be used with caution in patients with reduced CYP2C19 activity.
 184 Published studies indicate that patients who are poor CYP2C19 metabolizers have a 4-fold increase in exposure to carisoprodol, and
 185 concomitant 50% reduced exposure to meprobamate compared to normal CYP2C19 metabolizers. The prevalence of poor
 186 metabolizers in Caucasians and African Americans is approximately 3-5% and in Asians is approximately 15-20%.

188 **13 NONCLINICAL TOXICOLOGY**

189 **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

190 Long term studies in animals have not been performed to evaluate the carcinogenic potential of carisoprodol.
 191 SOMA was not formally evaluated for genotoxicity. In published studies, carisoprodol was mutagenic in the *in vitro* mouse
 192 lymphoma cell assay in the absence of metabolizing enzymes, but was not mutagenic in the presence of metabolizing enzymes.
 193 Carisoprodol was clastogenic in the *in vitro* chromosomal aberration assay using Chinese hamster ovary cells with or without the
 194 presence of metabolizing enzymes. Other types of genotoxic tests resulted in negative findings. Carisoprodol was not mutagenic in the
 195 Ames reverse mutation assay using *S. typhimurium* strains with or without metabolizing enzymes, and was not clastogenic in an *in*
 196 *vivo* mouse micronucleus assay of circulating blood cells.

197 SOMA was not formally evaluated for effects on fertility. Published reproductive studies of carisoprodol in mice found no
 198 alteration in fertility although an alteration in reproductive cycles characterized by a greater time spent in estrus was observed at a
 199 carisoprodol dose of 1200 mg/kg/day. In a 13-week toxicology study that did not determine fertility, mouse testes weight and sperm
 200 motility were reduced at a dose of 1200 mg/kg/day. In both studies, the no effect level was 750 mg/kg/day, corresponding to
 201 approximately 2.6 times the human equivalent dosage of 350 mg four times a day, based on mg/m^2 body surface area comparison.
 202 The significance of these findings for human fertility is not known.

204 **14 CLINICAL STUDIES**

205 The safety and efficacy of SOMA for the relief of acute, idiopathic mechanical low back pain was evaluated in two, 7-day,
 206 double blind, randomized, multicenter, placebo controlled, U.S. trials (Studies 1 and 2). Patients had to be 18 to 65 years old and had
 207 to have acute back pain (≤ 3 days of duration) to be included in the trials. Patients with chronic back pain; at increased risk for
 208 vertebral fracture (e.g., history of osteoporosis); with a history of spinal pathology (e.g., herniated nucleus pulposus, spondylolisthesis
 209 or spinal stenosis); with inflammatory back pain, or with evidence of a neurologic deficit were excluded from participation.
 210 Concomitant use of analgesics (e.g., acetaminophen, NSAIDs, tramadol, opioid agonists), other muscle relaxants, botulinum toxin,
 211 sedatives (e.g., barbiturates, benzodiazepines, promethazine hydrochloride), and anti-epileptic drugs was prohibited.

212 In Study 1, patients were randomized to one of three treatment groups (i.e., SOMA 250 mg, SOMA 350 mg, or placebo) and
 213 in Study 2 patients were randomized to two treatment groups (i.e., SOMA 250 mg or placebo). In both studies, patients received study
 214 medication three times a day and at bedtime for seven days.

215 The primary endpoints were the relief from starting backache and the global impression of change, as reported by patients, on
 216 ~~study Study day Day~~ #3. Both endpoints were scored on a 5-point rating scale from 0 (worst outcome) to 4 (best outcome) in both
 217 studies. The primary statistical comparison was between the SOMA 250 mg and placebo groups in both studies.

218 The proportion of patients who used concomitant acetaminophen, NSAIDs, tramadol, opioid agonists, other muscle relaxants,
 219 and benzodiazepines was similar in the treatment groups.

220 The results for the primary efficacy evaluations in the acute, low back pain studies are presented in Table 3.

221

Study	Parameter	Placebo	SOMA 250 mg	SOMA 350 mg
1	Number of Patients	n=269	n=264	n=273
	Relief from Starting Backache, Mean (SE) ^b	1.4 (0.1)	1.8 (0.1)	1.8 (0.1)
	Difference between SOMA and Placebo, Mean (SE) ^b (95% CI)		0.4 (0.2, 0.5)	0.4 (0.2, 0.6)
	Global Impression of Change, Mean (SE) ^b	1.9 (0.1)	2.2 (0.1)	2.2 (0.1)
	Difference between SOMA and Placebo, Mean (SE) ^b (95% CI)		0.2 (0.1, 0.4)	0.3 (0.1, 0.4)
2	Number of Patients	n=278	n=269	
	Relief from Starting Backache, Mean (SE) ^b	1.1 (0.1)	1.8 (0.1)	
	Difference between SOMA and Placebo, Mean (SE) ^b (95% CI)		0.7 (0.5, 0.9)	
	Global Impression of Change, Mean (SE) ^b	1.7 (0.1)	2.2 (0.1)	
	Difference between SOMA and Placebo, Mean (SE) ^b (95% CI)		0.5 (0.4, 0.7)	

222 a The primary efficacy endpoints (Relief from Starting Backache and Global Impression of
 223 Change) were assessed by the patients on Study Day #3. These endpoints were scored on a 5-point rating scale from 0 (worst
 224 outcome) to 4 (best outcome).

225 b Mean is the least squared mean and SE is the standard error of the mean. The ANOVA model was used for the primary statistical
 226 comparison between the SOMA 250 mg and placebo groups.

227 Patients treated with SOMA experienced improvement in function as measured by the Roland-Morris Disability
 228 Questionnaire (RMDQ) score on Days 3 and 7.

230 **16 HOW SUPPLIED/STORAGE AND HANDLING**

231 250mg Tablets: round, convex, white tablets, inscribed with SOMA 250; available in bottles of 100 (NDC 0037-2250-10).

232 350mg Tablets: round, convex, white tablets, inscribed with SOMA 350; available in bottles of 100 (NDC 0037-2001-01).

233

234
235
236
237
238
239
240
241
242
243
244
245
246
247
248
249
250
251
252
253
254

Storage:
Store at 25 °C (77 °F); excursions permitted between 15 °C and 30 °C (59 °F and 86 °F) (see USP Controlled Room Temperature).

17 PATIENT COUNSELING INFORMATION

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

17.1 Sedation

Since SOMA may cause drowsiness and/or dizziness, patients should be advised to assess their individual response to SOMA before engaging in potentially hazardous activities such as driving a motor vehicle or operating machinery [see *Warnings and Precautions (5.1)*].

17.2 Avoidance of Alcohol and Other CNS Depressants

Patients should be advised to avoid alcoholic beverages while taking SOMA 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)*].

17.3 SOMA Should Only ~~be~~ Be Used for Short-Term Treatment

Patients should be advised that treatment with SOMA should be limited to acute use (up to two or three weeks) for the relief of acute, musculoskeletal discomfort. If symptoms still persist, patients should contact their healthcare provider for further evaluation.

MedPointe Pharmaceuticals
MedPointe Healthcare Inc.
Somerset, NJ 08873

LB-9062-03
Rev. 7/07

Please see enclosed full Prescribing Information

Dispense in light container.
Store at controlled room temperature
20°-25°C (68°-77°F).

MedPointe
Pharmaceuticals, Inc.
Somerset, New Jersey 08873

 **SOMA** 250 mg
Carisoprodol Tablets

NDC 0037-2250-10

100 Tablets **Rx Only**

 0037-2250-10

1/2" Non-Varnish Area

Ⓢ MedPointe 1-1/2" x 3-3/4" (4)

7-10-2007

06 07 08 09 10 11 12
1 2 3 4 5 6 7 8 9 10 12



SC-90G4-02
Rev. 7/07



Rx Only

Please see package insert for
full Prescribing Information.

SOMA 250 MG
Carisoprodol Tablets

2-3/4" x 1" Non-Varnish Area



SOMA 250 MG
Carisoprodol Tablets

medPointe
pharmaceuticals®
medPointe Healthcare Inc.
Somerset, New Jersey 08873

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



Rx Only

NDC 0037-2250-24

4
TABLETS

SOMA 250 MG
Carisoprodol Tablets

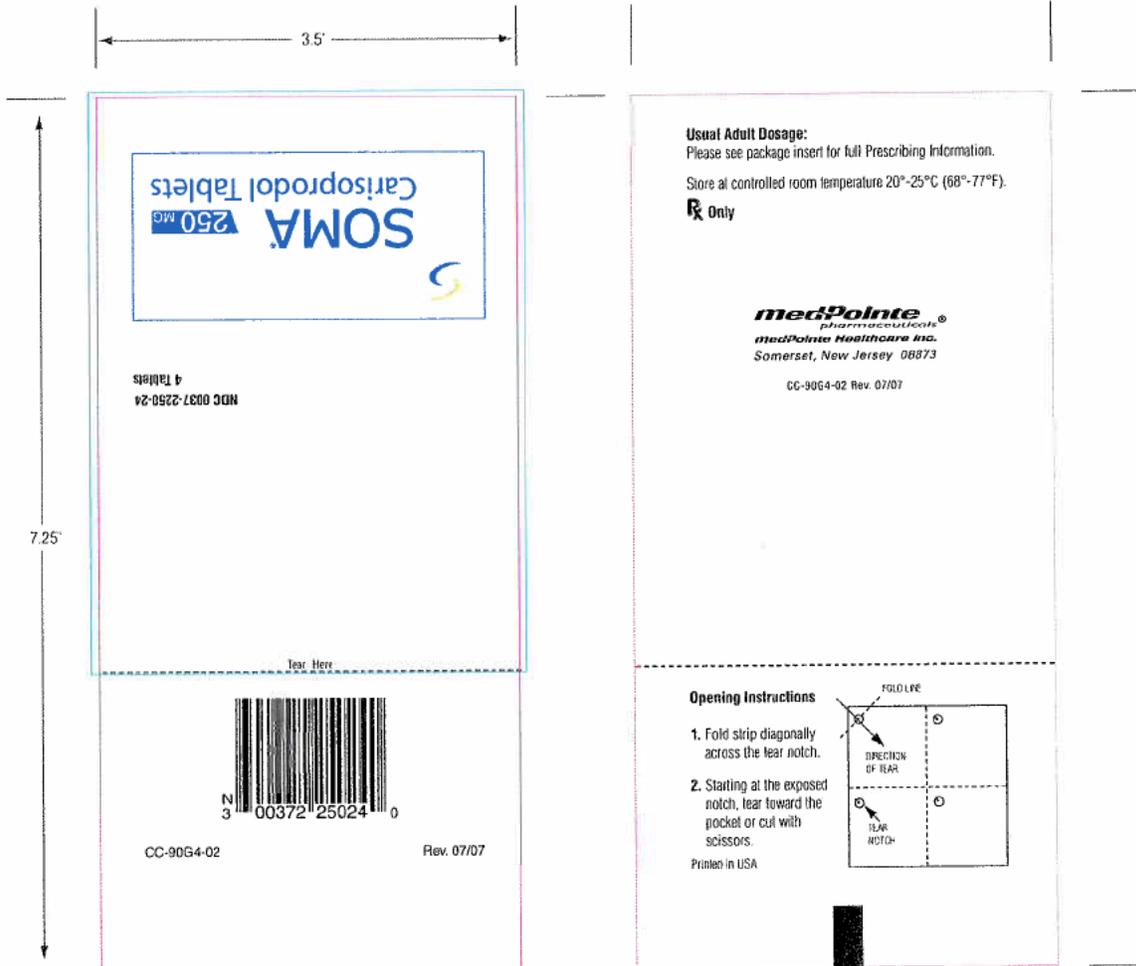
SOMA 250 MG
Carisoprodol Tablets



N 3 00372 25024 0

MedPointe
Folded: 3 5/8" w x 3 3/4" h x 3/4" d

7-10-2007



CUSTOMER: MEDPOINTE, INC.	
DATE : 07/10/07	ITEM #: CC-90G4-02
PRODUCT: SOMA 250 TRADE CATCHCOVER 4 TABLETS	
DIMENSIONS: 3.5 X 7.25 INCHES	
(b) (4)	

- PATTERN VARNISH
- THIS LASERPROOF INDICATES COLORBREAKS ONLY AND MAY NOT ACCURATELY REFLECT ACTUAL PRODUCTION COLORS
- DIE LINES SHOWN FOR REFERENCE ONLY — DOES NOT PRINT

MedPointe
Folded: 3 5/8" w x 3 3/4" h x 3/4" d

7-10-2007



Date _____ Patient _____
Directions _____ Practitioner _____

Rx Only



NDC 0037-2250-04

4
TABLETS

PHYSICIAN SAMPLE - NOT FOR SALE

SOMA 250 MG
Carisoprodol Tablets

SOMA 250 MG
Carisoprodol Tablets



SOMA 250 MG
Carisoprodol Tablets

Rx Only



Please see package insert for
full Prescribing Information.

SOMA 250 MG
Carisoprodol Tablets

2-3/4" x 1" Non-varnish Area

SC-90CB-03
Rev. 7/07



06 07 08 09 10 11 12
1 2 3 4 5 6 7 8 9 10 11 12

medpointe
pharmaceuticals
Somerset, New Jersey 08873
Store at controlled
room temperature
20°-25°C (68°-77°F).

- PATTERN VARNISH
- THIS LASERPROOF INDICATES COLORBREAKS ONLY AND MAY NOT ACCURATELY REFLECT ACTUAL PRODUCTION COLORS
- DIE LINES SHOWN FOR REFERENCE ONLY — DOES NOT PRINT

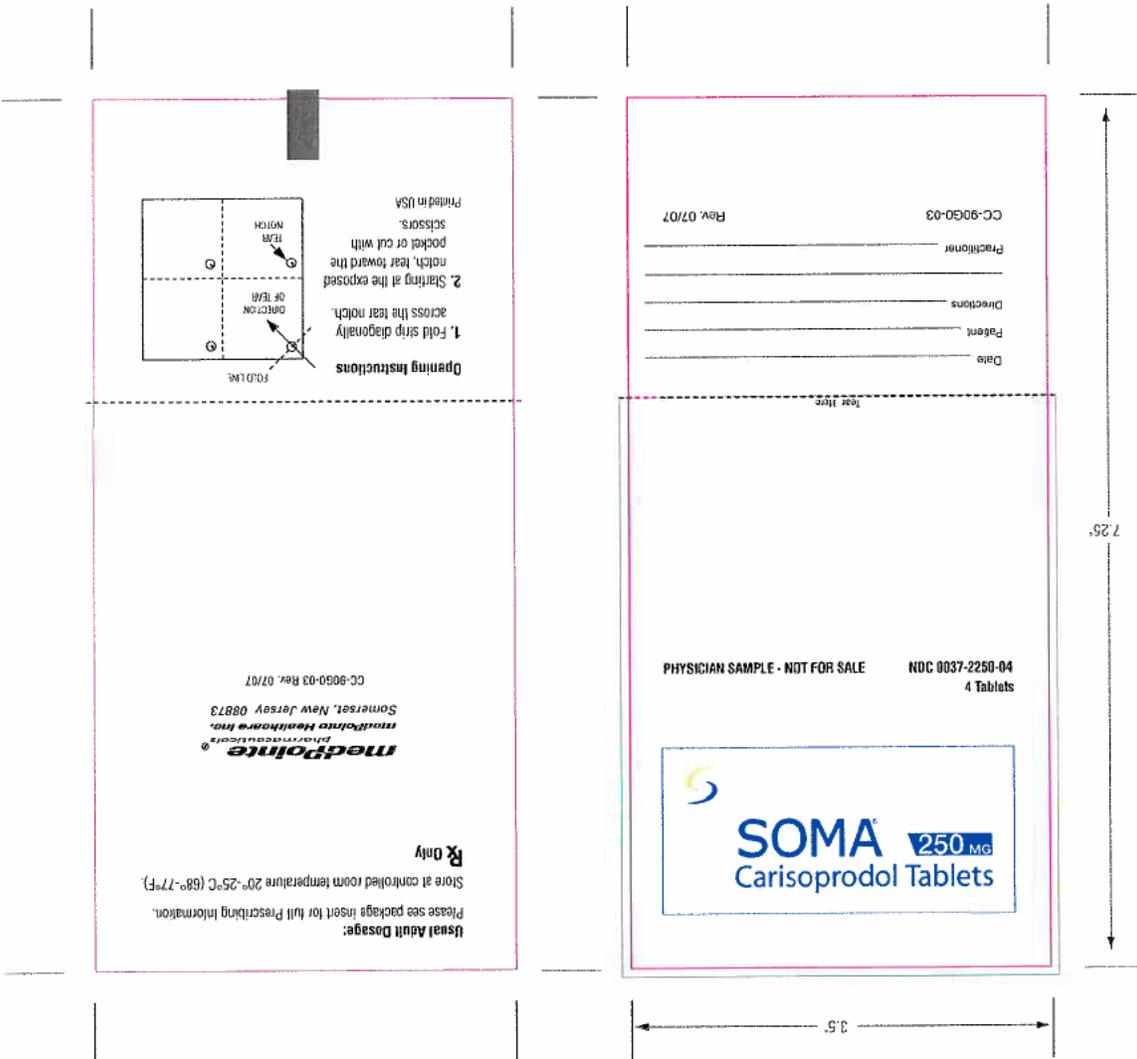
CUSTOMER: MEDPOINTE, INC.

DATE: 07/10/07
 ITEM #: CC-9060-03

PRODUCT: SOMA 250 CATCHCOVER 4 TABLETS - PHYSICIAN SAMPLE

DIMENSIONS: 3.5 X 7.25 INCHES

(b) (4)





SOMA[®] 250 MG
Carisoprodol Tablets



Rx Only

Please see package insert for full Prescribing Information.

SOMA[®] 250 MG
Carisoprodol Tablets

2-3/4" x 1" Non-Varnish Area

SC-90GS-02
Rev. 7/07

06 07 08 09 10 11 12
1 2 3 4 5 6 7 8 9 10 12



medPointe[®]
pharmaceuticals
medPointe Healthcare Inc.
Somerset, New Jersey 08873

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

MedPointe #46958
Soma 250 28 count,
dip front, long tuck, RTE
3 5/8" x 1 1/2" x 3 3/4"
Flat: 10 25/32" x 8 29/32"
.016 SBS C1S **PRINT SIDE**



7-10-2007

Rx Only

NDC-0037-2250-28

PHYSICIAN SAMPLE - NOT FOR SALE

28
TABLETS

SOMA[®] 250 MG
Carisoprodol Tablets



SOMA[®] 250 MG
Carisoprodol Tablets

Directions _____

Practitioner _____

Date _____

Patient _____

SOMA®
Carisoprodol Tablets
250 mg
Pouch Labeling

<p>SOMA® Carisoprodol Tablets, 250mg Lot XXXXXXXXXXXX Exp MM/YYYY</p>	<p>SOMA® Carisoprodol Tablets, 250mg Lot XXXXXXXXXXXX Exp MM/YYYY</p>
<p>SOMA® Carisoprodol Tablets, 250mg Lot XXXXXXXXXXXX Exp MM/YYYY</p>	<p>SOMA® Carisoprodol Tablets, 250mg Lot XXXXXXXXXXXX Exp MM/YYYY</p>

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Rigoberto Roca
9/13/2007 05:17:47 PM