

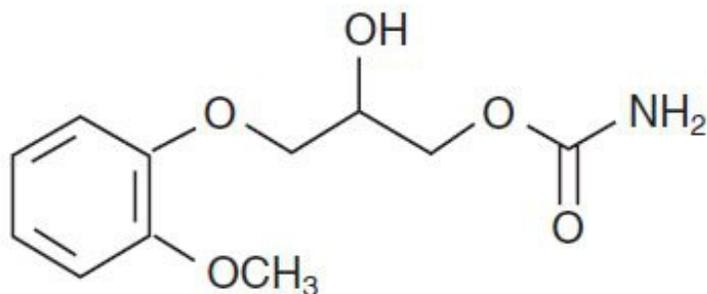
METHOCARBAMOL- methocarbamol tablet, film coated
NCS HealthCare of KY, LLC dba Vanguard Labs

Methocarbamol Tablets, USP

DESCRIPTION

Methocarbamol Tablets, USP, a carbamate derivative of guaifenesin, is a central nervous system (CNS) depressant with sedative and musculoskeletal relaxant properties.

The chemical name of methocarbamol is 3-(2-methoxyphenoxy)-1,2-propanediol 1-carbamate and has the empirical formula $C_{11}H_{15}NO_5$. Its molecular weight is 241.24. The structural formula is shown below.



Methocarbamol is a white powder, sparingly soluble in water and chloroform, soluble in alcohol (only with heating) and propylene glycol, and insoluble in benzene and *n*-hexane.

Methocarbamol tablet USP, 500 mg is available as a white, round, scored, film-coated tablet, debossed "ASC" over the score on one side and "500" on the other side.

Methocarbamol tablet USP, 750 mg is available as white, capsule-shaped, film-coated tablet, debossed "ASC" on one side and "750" on the other side.

Each tablet for oral administration contains 500 mg or 750 mg methocarbamol. Inactive ingredients include colloidal silicon dioxide, croscarmellose sodium, lecithin, magnesium stearate, microcrystalline cellulose, povidone, polyvinyl alcohol, polyethylene glycol, sodium lauryl sulfate, talc and titanium dioxide.

CLINICAL PHARMACOLOGY

The mechanism of action of methocarbamol in humans has not been established, but may be due to general CNS depression. It has no direct action on the contractile mechanism of striated muscle, the motor end plate or the nerve fiber.

Pharmacokinetics

In healthy volunteers, the plasma clearance of methocarbamol ranges between 0.20 and

0.80 L/h/kg, the mean plasma elimination half-life ranges between 1 and 2 hours, and the plasma protein binding ranges between 46% and 50%.

Methocarbamol is metabolized via dealkylation and hydroxylation. Conjugation of methocarbamol also is likely. Essentially all methocarbamol metabolites are eliminated in the urine. Small amounts of unchanged methocarbamol also are excreted in the urine.

Special populations

Elderly

The mean [\pm SD] elimination half-life of methocarbamol in elderly healthy volunteers (mean [\pm SD] age, 69 [\pm 4] years) was slightly prolonged compared to a younger (mean [\pm SD] age, 53.3 [\pm 8.8] years), healthy population (1.5 [\pm 0.4] hours versus 1.1 [\pm 0.27] hours, respectively). The fraction of bound methocarbamol was slightly decreased in the elderly versus younger volunteers (41% to 43% versus 46% to 50%, respectively).

Renally impaired

The clearance of methocarbamol in 8 renally-impaired patients on maintenance hemodialysis was reduced about 40% compared to 17 normal subjects, although the mean (\pm SD) elimination half-life in these two groups was similar: 1.2 (\pm 0.6) versus 1.1 (\pm 0.3) hours, respectively.

Hepatically impaired

In 8 patients with cirrhosis secondary to alcohol abuse, the mean total clearance of methocarbamol was reduced approximately 70% compared to that obtained in 8 age- and weight-matched normal subjects. The mean (\pm SD) elimination half-life in the cirrhotic patients and the normal subjects was 3.38 (\pm 1.62) hours and 1.11 (\pm 0.27) hours, respectively. The percent of methocarbamol bound to plasma proteins was decreased to approximately 40% to 45% compared to 46% to 50% in the normal subjects.

INDICATIONS AND USAGE

Methocarbamol 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 methocarbamol has not been clearly identified, but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man.

CONTRAINDICATIONS

Methocarbamol is contraindicated in patients hypersensitive to methocarbamol or to any of the tablet components.

WARNINGS

Since methocarbamol may possess a general CNS depressant effect, patients receiving methocarbamol should be cautioned about combined effects with alcohol and other CNS depressants.

Safe use of methocarbamol has not been established with regard to possible adverse effects upon fetal development. There have been reports of fetal and congenital abnormalities following in utero exposure to methocarbamol. Therefore, methocarbamol should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards (see **PRECAUTION, Pregnancy**).

Use in Activities Requiring Mental Alertness

Methocarbamol may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle. Patients should be cautioned about operating machinery, including automobiles, until they are reasonably certain that methocarbamol therapy does not adversely affect their ability to engage in such activities.

PRECAUTIONS

Information for Patients

Patients should be cautioned that methocarbamol may cause drowsiness or dizziness, which may impair their ability to operate motor vehicles or machinery. Because methocarbamol may possess a general CNS-depressant effect, patients should be cautioned about combined effects with alcohol and other CNS depressants.

Drug Interactions

See **WARNINGS** and **PRECAUTIONS** for interaction with CNS drugs and alcohol.

Methocarbamol may inhibit the effect of pyridostigmine bromide. Therefore, methocarbamol should be used with caution in patients with myasthenia gravis receiving anticholinesterase agents.

Drug/Laboratory Test Interactions

Methocarbamol may cause a color interference in certain screening tests for 5-hydroxyindoleacetic acid (5-HIAA) using nitrosonaphthol reagent and in screening tests for urinary vanillylmandelic acid (VMA) using the Gitlow method.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies to evaluate the carcinogenic potential of methocarbamol have not been performed. No studies have been conducted to assess the effect of methocarbamol on mutagenesis or its potential to impair fertility.

Pregnancy

Teratogenic Effects

Animal reproduction studies have not been conducted with methocarbamol. It is also not known whether methocarbamol can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Methocarbamol should be given to a pregnant woman only if clearly needed.

Safe use of Methocarbamol has not been established with regard to possible adverse effects upon fetal development. There have been reports of fetal and congenital abnormalities following in utero exposure to methocarbamol. Therefore, Methocarbamol should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards (see **WARNINGS**).

Nursing Mothers

Methocarbamol and/or its metabolites are excreted in the milk of dogs; however, it is not known whether methocarbamol or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when methocarbamol is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of methocarbamol in pediatric patients below the age of 16 have not been established.

ADVERSE REACTIONS

Adverse reactions reported coincident with the administration of methocarbamol include:

Body as a whole: Anaphylactic reaction, angioneurotic edema, fever, headache

Cardiovascular system: Bradycardia, flushing, hypotension, syncope, thrombophlebitis

Digestive system: Dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting

Hemic and lymphatic system: Leukopenia

Immune system: Hypersensitivity reactions

Nervous system: Amnesia, confusion, diplopia, dizziness or lightheadedness, drowsiness, insomnia, mild muscular incoordination, nystagmus, sedation, seizures (including grand mal), vertigo

Skin and special senses: Blurred vision, conjunctivitis, nasal congestion, metallic taste, pruritus, rash, urticaria

OVERDOSAGE

Limited information is available on the acute toxicity of methocarbamol. Overdose of methocarbamol is frequently in conjunction with alcohol or other CNS depressants and includes the following symptoms: nausea, drowsiness, blurred vision, hypotension, seizures, and coma.

In post-marketing experience, deaths have been reported with an overdose of methocarbamol alone or in the presence of other CNS depressants, alcohol or psychotropic drugs.

Treatment

Management of overdose includes symptomatic and supportive treatment. Supportive measures include maintenance of an adequate airway, monitoring urinary output and vital signs, and administration of intravenous fluids if necessary. The usefulness of

hemodialysis in managing overdose is unknown.

DOSAGE AND ADMINISTRATION

Methocarbamol 500 mg - Adults:

Initial dosage: 3 tablets 4 times a day

Maintenance dosage: 2 tablets 4 times a day

750 mg - Adults:

Initial dosage: 2 tablets 4 times a day

Maintenance dosage: 1 tablet every 4 hours, or 2 tablets 3 times a day.

Six grams a day are recommended for the first 48 to 72 hours of treatment. (For severe conditions 8 grams a day may be administered.) Thereafter, the dosage can usually be reduced to approximately 4 grams a day.

HOW SUPPLIED

Methocarbamol tablets, USP 500 mg are white, round, scored, film-coated tablets, debossed "ASC" over the score on one side and "500" on the other side. They are supplied as follows:

Blistercards of 30: NDC 0615-8435-39

Methocarbamol tablets, USP 750 mg are white, capsule-shaped, film-coated tablets, debossed "ASC" on one side and 750 on the other.

Store between 20°C and 25°C (68°F and 77°F) [see USP Controlled Room Temperature]. Dispense in a tight container.

Manufactured For:

DBL Pharmaceuticals, Inc.

Jackson Heights, NY 11372

For more information, call ACI Healthcare USA, Inc. at 1-888-802-1213.

Manufactured By:

Cohance Lifesciences Limited

Telangana - 500076, INDIA.

Distributed By:

ACI Healthcare USA, Inc.

10100 W. Sample Road, Suite 406

Coral Springs, FL 33065

Issued February 2023

PRINCIPAL DISPLAY PANEL



VLI NDC 0615-8435-39
Methocarbamol
Tabs USP 500 mg



LOT 8435-
EXP

8435-AA-39 v01

QTY
30

Mfg By Cohance for
ACI
(NDC 71093-140-05)
PKG BY VANGARD
GLASGOW, KY 42141

(ACI NDC 71093-140-05)
Methocarbamol
Tabs USP 500 mg

Rx only

			16	8
30	23	15	7	
29	22	14	6	
28	21	13	5	
27	20	12	4	
26	19	11	3	
25	18	10	2	
	24	17	9	1



The overall configuration of this package is a trademark of Omnicare, Inc.

Received: _____

31	24	16	8
30	23	15	7
29	22	14	6
28	21	13	5
27	20	12	4
26	19	11	3
25	18	10	2
24	17	9	1

Start Date _____ Start Time _____

STORE AT 20° - 25°C (68° - 77° F)
(SEE USP CONTROLLED ROOM TEMPERATURE)

Dispense in a tight container.

Each tablet contains:
Methocarbamol 500 mg

See package insert or label for dosage information
FOR INSTITUTIONAL USE ONLY

<p>Pkg by Vanguard, Glasgow, KY 42141 Methocarbamol Tab USP 500 mg LOT 8435- EXP 7109314005</p>	<p>Pkg by Vanguard, Glasgow, KY 42141 Methocarbamol Tab USP 500 mg LOT 8435- EXP 7109314005</p>	<p>Pkg by Vanguard, Glasgow, KY 42141 Methocarbamol Tab USP 500 mg LOT 8435- EXP 7109314005</p>	<p>8435-AA-B-v01 Vanguard Labs Glasgow, KY 42141 LOT 8435- EXP 7109314005</p>
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METHOCARBAMOL

methocarbamol tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0615-8435(NDC:71093-140)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHOCARBAMOL (UNII: 125OD7737X) (METHOCARBAMOL - UNII:125OD7737X)	METHOCARBAMOL	500 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	13mm
Flavor		Imprint Code	ASC;500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-8435-39	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/14/2022	07/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203550	02/08/2017	07/31/2024

Labeler - NCS HealthCare of KY, LLC dba Vanguard Labs (050052943)

Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, LLC dba Vanguard Labs		050052943	repack(0615-8435)

Revised: 6/2023

NCS HealthCare of KY, LLC dba Vanguard Labs