

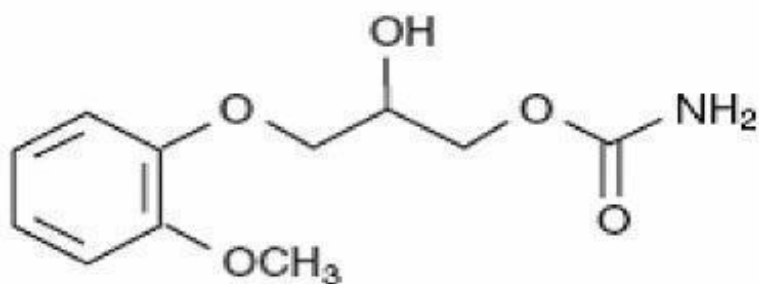
METHOCARBAMOL- methocarbamol tablet, film coated
Golden State Medical Supply, Inc.

Methocarbamol Tablets USP

DESCRIPTION

Methocarbamol Tablets USP, 500 mg and 750 mg, a carbamate derivative of guafenesin, is a central nervous system (CNS) depressant with sedative and musculoskeletal relaxant properties.

The chemical name of methocarbamol is a 3-(2 methoxyphenoxy)-1,2-propanediol 1-carbamate and has the empirical formula C₁₁H₁₅NO₅. 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, 500 mg is available as an orange, film coated, round concave tablet containing 500 mg of methocarbamol, USP for oral administration. The inactive ingredients present are microcrystalline cellulose, croscarmellose sodium, FD&C Yellow 6 aluminum lake, hydroxypropyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, triacetin, titanium dioxide.

Methocarbamol Tablet, 750 mg is available as a yellow, film coated, modified capsule shaped tablet containing 750 mg of methocarbamol, USP for oral administration. The inactive ingredients present are microcrystalline cellulose, croscarmellose sodium, iron oxide yellow, iron oxide red, hydroxypropyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, triacetin, titanium dioxide.

Clinical Pharmacology

The mechanism of action of methocarbamol in humans has not been established, but may be due to general central nervous system (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).

Preclinical studies (in male rats) show that alendronate transiently distributes to soft tissues following 1 mg/kg IV administration but is then rapidly redistributed to bone or excreted in the urine. The mean steady-state volume of distribution, exclusive of bone, is at least 28 L in humans. Concentrations of drug in plasma following therapeutic oral doses are too low (less than 5 ng/mL) for analytical detection. Protein binding in human plasma is approximately 78%.

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 tablets 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 tablets 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 PRECAUTIONS, 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 — Pregnancy Category C

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 q.i.d.
Maintenance dosage: 2 tablets q.i.d.

Methocarbamol, 750 mg — Adults:
Initial dosage: 2 tablets q.i.d.
Maintenance dosage: 1 tablet q.4h. or 2 tablets t.i.d.

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 — Orange, film coated, round concave tablets with one side debossed 'AP212', the other side bisected. Available in bottles of 100 and 500.

Methocarbamol Tablets USP, 750 mg — Yellow, film coated, modified capsule shaped tablets; one side debossed 'AP211' and other side blank. Available in bottles of 100 and 500.

Store at 20° to 25°C (68° to 77°F) [See USP controlled room temperature].

Dispense in a tight container.

LBL136

100318

October, 2018

Manufactured by:

AustarPharma, LLC

18 Mayfield Ave

Edison, NJ 08837, USA

Marketed/Packaged by:

GSMS, Inc.

Camarillo, CA USA 93012



Principal Display Panel - 500mg 500 counts

NDC: 60429-118-05

Methocarbamol

500mg 500 tablet (s)

RX only

<i>GSMS Incorporated GSMS Incorporated GSMS Incorporated GSMS Incorporated GSMS Incorporated</i>				
<p>Manufactured by AustarPharma, LLC Edison, NJ 08837, USA Marketed by GSMS, Inc. Incorporated Camarillo, CA 93012, USA</p> 	<p>GTIN: LOT: EXP: SN:</p>	<p>• Each tablet contains: 500 mg Methocarbamol. • USUAL ADULT DOSAGE: Two to four tablets four times daily. • See accompanying descriptive literature. • Keep this and all medication out of the reach of children. • Dispense in a light container.</p>	 6042911805	<p>NDC 60429-118-05 METHOCARBAMOL TABLETS, USP 500 mg 500 tablets</p> <p>See package insert for dosage information.</p>
				<p>Store at 20° to 25°C (68° to 77°F) [See USP controlled room temperature].</p> <p>Rx only</p>

Principal Display Panel - 750mg 500counts

NDC: 60429-119-05

Methocarbamol

750mg 500tablet (s)

RX only

GSMS Incorporated


GSMS Incorporated

GSMS Incorporated

GSMS Incorporated


GSMS Incorporated

Manufactured by AuroaPharma LLC
Edison, NJ 08837, USA
Packaged by GSMS, Incorporated
Camarillo, CA 93012, USA



GTIN:
LOT:
EXP:
SN:

- Each tablet contains:
750 mg Methocarbamol.
- **USUAL ADULT DOSAGE:**
Two tablets three times daily.
See accompanying descriptive literature.
- Keep this and all medication out of
the reach of children.
- Dispense in a tight container.


6042911905

NDC 60429-119-05
METHOCARBAMOL
TABLETS, USP
750 mg
500 tablets

See package insert for dosage information.

Store at 20° to 25°C (68° to 77°F)
[See USP controlled room temperature].

Rx only

METHOCARBAMOL

methocarbamol tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60429-119(NDC:35561-211)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
METHOCARBAMOL (UNII: 125OD7737X) (METHOCARBAMOL - UNII:125OD7737X)		METHOCARBAMOL	750 mg	
Product Characteristics				
Color	yellow	Score	no score	
Shape	CAPSULE	Size	19mm	
Flavor		Imprint Code	AP211	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60429-119-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2014	04/30/2024
2	NDC:60429-119-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2014	04/30/2024
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA200958	10/21/2011	04/30/2024

METHOCARBAMOL			
methocarbamol tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60429-118(NDC:35561-212)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
METHOCARBAMOL (UNII: 125OD7737X) (METHOCARBAMOL - UNII:125OD7737X)		METHOCARBAMOL	500 mg
Product Characteristics			
Color	orange	Score	2 pieces
Shape	ROUND	Size	13mm
Flavor		Imprint Code	AP212
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60429-118-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2014	05/31/2017
2	NDC:60429-118-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2014	01/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200958	10/21/2011	01/31/2024

Labeler - Golden State Medical Supply, Inc. (603184490)

Establishment

Name	Address	ID/FEI	Business Operations
Golden State Medical Supply, Inc.		603184490	relabel(60429-118, 60429-119) , repack(60429-118, 60429-119)

Revised: 3/2022

Golden State Medical Supply, Inc.