

METHOCARBAMOL- methocarbamol tablet
Bryant Ranch Prepack

Methocarbamol Tablets

METHOCARBAMOL TABLETS, USP

Rev. 03/16

Rx Only

DESCRIPTION:

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



The chemical name for 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.

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.

Each tablet, for oral administration, contains 500 mg or 750 mg of methocarbamol, USP. In addition each tablet contains the following inactive ingredients: Colloidal Silicon Dioxide, Lactose Monohydrate, Magnesium Stearate, Methylcellulose, Microcrystalline Cellulose, Pregelatinized Starch and Sodium Starch Glycolate.

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).

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 Tablets are 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 Tablets are 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 Tablets 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 Tablets should be given to a pregnant woman only if clearly needed.

Safe use of Methocarbamol Tablets 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 **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 Tablets are administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Methocarbamol Tablets 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

To report SUSPECTED ADVERSE REACTIONS, contact West-Ward Pharmaceuticals Corp. at 1-877-233-2001, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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:

500 mg – Adults: Initial dosage, 3 tablets four times a day; maintenance dosage, 2 tablets four times a day.

750 mg – Adults: Initial dosage, 2 tablets four times a day; maintenance dosage, 1 tablet every four hours or 2 tablets three 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:

Product: 71335-0771

NDC: 71335-0771-0 14 TABLET in a BOTTLE

NDC: 71335-0771-1 20 TABLET in a BOTTLE

NDC: 71335-0771-2 30 TABLET in a BOTTLE

NDC: 71335-0771-3 40 TABLET in a BOTTLE

NDC: 71335-0771-4 120 TABLET in a BOTTLE

NDC: 71335-0771-5 60 TABLET in a BOTTLE

NDC: 71335-0771-6 90 TABLET in a BOTTLE

NDC: 71335-0771-7 112 TABLET in a BOTTLE

NDC: 71335-0771-8 21 TABLET in a BOTTLE

NDC: 71335-0771-9 84 TABLET in a BOTTLE

Product: 71335-0844

NDC: 71335-0844-0 15 TABLET in a BOTTLE

NDC: 71335-0844-1 14 TABLET in a BOTTLE

NDC: 71335-0844-2 30 TABLET in a BOTTLE

NDC: 71335-0844-3 20 TABLET in a BOTTLE

NDC: 71335-0844-4 60 TABLET in a BOTTLE

NDC: 71335-0844-9 7 TABLET in a BOTTLE

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71335-0771(NDC:0143-1292)
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
METHOCARBAMOL (UNII: 125OD7737X) (METHOCARBAMOL - UNII:125OD7737X)		METHOCARBAMOL	750 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
METHYLCELLULOSE (100 MPA.S) (UNII: 4GFU244C4J)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
STARCH, CORN (UNII: O8232NY3SJ)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
Product Characteristics				
Color	WHITE (WHITE)	Score	2 pieces	
Shape	OVAL (Capsule)	Size	27mm	
Flavor		Imprint Code	West;ward;292	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-0771-2	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2005	
2	NDC:71335-0771-8	21 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2005	
3	NDC:71335-0771-5	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2005	
4	NDC:71335-0771-0	14 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2005	
5	NDC:71335-0771-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2005	
6	NDC:71335-0771-3	40 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2005	
7	NDC:71335-0771-9	84 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2005	
8	NDC:71335-0771-4	120 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2005	
9	NDC:71335-0771-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2005	
10	NDC:71335-0771-7	112 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2005	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA085123		01/01/2000	

METHOCARBAMOL

methocarbamol tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71335-0844(NDC:0143-1290)
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)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLCELLULOSE (100 MPA.S) (UNII: 4GFU244C4J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	20mm
Flavor		Imprint Code	West;ward;290
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-0844-6	40 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2005	
2	NDC:71335-0844-3	20 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2005	
3	NDC:71335-0844-9	7 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2005	
4	NDC:71335-0844-4	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2005	
5	NDC:71335-0844-7	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2005	
6	NDC:71335-0844-1	14 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2005	
7	NDC:71335-0844-8	120 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2005	
8	NDC:71335-0844-2	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2005	
9	NDC:71335-0844-5	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2005	
10	NDC:71335-0844-0	15 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA085159	01/01/2000	

Labeler - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-0771, 71335-0844) , RELABEL(71335-0771, 71335-0844)

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Bryant Ranch Prepack