

**METHOCARBAMOL - methocarbamol tablet**  
**Keltman Pharmaceuticals Inc.**

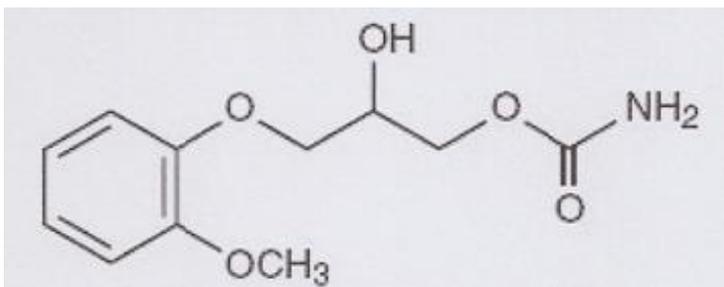
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**Methocarbamol Tablets**

**METHOCARBAMOL TABLETS, USP**

**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<sub>11</sub>H<sub>15</sub>NO<sub>5</sub>. 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

## 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 q.i.d.; maintenance dosage, 2 tablets q.i.d.

**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 500 mg: White, Round, Scored, Compressed Tablet; Debossed “West-ward 290”

Methocarbamol Tablets 750 mg: White, Capsule Shaped, Scored Tablet; Debossed “West-ward 292”

They are supplied by **Keltman Pharmaceuticals Inc.** as follows:

NDC	Strength	Quantity/Form	Color	Source Prod. Code
68387-342-60	500 mg	60 Tablets in a Plastic Bottle	WHITE	0143-1290
68387-340-30	750 mg	30 Tablets in a Plastic Bottle	WHITE	0143-1292
68387-340-45	750 mg	45 Tablets in a Plastic Bottle	WHITE	0143-1292
68387-340-60	750 mg	60 Tablets in a Plastic Bottle	WHITE	0143-1292
68387-340-90	750 mg	90 Tablets in a Plastic Bottle	WHITE	0143-1292
68387-340-24	750 mg	240 Tablets in a Plastic Bottle	WHITE	0143-1292

Store at 20-25°C (68-77°F) [See USP Controlled Room Temperature]. Protect from light and moisture.  
Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Manufactured by:

**West-ward Pharmaceutical Corp.**

Eatontown, NJ 07724

This Product was Repackaged By Sandhills Packaging For:

**Keltman Pharmaceuticals Inc.**

1 Lakeland Square, Suite A

Flowood, MS 39232

United States

**Methocarbamol Tablets, USP 500 mg**

**Keltman Pharmaceuticals, Inc.**

NDC: 68387-342-60  
**Methocarbamol 500mg**  
Generic Robaxin 500mg  
**60 Tablets**  
Each tablet contains 500mg methocarbamol

**Rx Only**

Lot: **66746A 1** Exp: **5/2013** Rx #: **52094**  
Store at controlled room temperature 20-25 C (68-77 F).  
Keep out of reach of children Dosage: See package insert  
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.

Manufactured by: West-ward Pharmaceutical Corp. Eatontown, NJ 07724  
Distributed by: Keltman Pharmaceuticals, Inc. Flowood, MS 39232  
Call your doctor for medical advice about side effects.  
You may report side effects to FDA at 1-800-FDA-1088.

68387-0342-60++66746A1

Take \_\_\_ tablet(s) \_\_\_ time(s) daily or every \_\_\_ hours for \_\_\_ days.

NDC: 68387-342-60 Rx #: 52094  
Generic Robaxin 500mg (methocarbamol)  
Lot: 66746A 1 Exp: 5/2013 Chart

NDC: 68387-342-60 Rx #: 52094  
Generic Robaxin 500mg (methocarbamol)  
Lot: 66746A 1 Exp: 5/2013 Patient

NDC: 68387-342-60 Rx #: 52094  
Generic Robaxin 500mg (methocarbamol)  
Lot: 66746A 1 Exp: 5/2013 Bill

NDC: 68387-342-60 Rx #: 52094  
Generic Robaxin 500mg (methocarbamol)  
Lot: 66746A 1 Exp: 5/2013 Log

**Methocarbamol Tablets, USP 500 mg**

**Methocarbamol Tablets, USP 750 mg**

# Keltman Pharmaceuticals, Inc.

68387-0340-24++67391A1



Take \_\_\_ tablet(s) \_\_\_ time(s) daily or  
every \_\_\_ hours for \_\_\_ days.

## NDC:68387-340-24 Methocarbamol 750mg

Generic Robaxin 750mg  
240 Tablets

Each tablet contains 750mg methocarbamol

Rx Only

Lot: 67391A 1 Exp: 11/2013 Rx #: 73089  
Store at controlled room temperature 20-25 C (68-77 F).

Keep out of reach of children. Dosage: See package insert  
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.

Manufactured by: West-ward Pharmaceutical Corp., Eatontown, NJ 07724  
Distributed by: Keltman Pharmaceuticals, Inc. Flowood, MS 39232  
Call your doctor for medical advice about side effects.  
You may report side effects to FDA at 1-800-FDA-1088.

NDC: 68387-340-24 Rx #: 73089  
Generic Robaxin 750mg (methocarbamol)

Lot: 67391A 1 Exp: 11/2013

NDC: 68387-340-24 Rx #: 73089  
Generic Robaxin 750mg (methocarbamol)

Lot: 67391A 1 Exp: 11/2013

NDC: 68387-340-24 Rx #: 73089  
Generic Robaxin 750mg (methocarbamol)

Lot: 67391A 1 Exp: 11/2013

NDC: 68387-340-24 Rx #: 73089  
Generic Robaxin 750mg (methocarbamol)

Lot: 67391A 1 Exp: 11/2013

Chart  
Patient  
Bill  
Log

### Methocarbamol Tablets, USP 750 mg

## METHOCARBAMOL

methocarbamol tablet

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68387-342(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
METHYLCELLULOSE (100 CPS) (UNII: 4GFU244C4J)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

### 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:68387-342-60	60 in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA085159	05/08/2009	

## METHOCARBAMOL

methocarbamol tablet

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68387-340(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
METHYLCELLULOSE (100 CPS) (UNII: 4GFU244C4J)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

### Product Characteristics

Color	WHITE (WHITE)	Score	2 pieces
Shape	OVAL (CAPSULE)	Size	27mm
Flavor		Imprint Code	Westward;292
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68387-340-30	30 in 1 BOTTLE, PLASTIC		
2	NDC:68387-340-45	45 in 1 BOTTLE, PLASTIC		
3	NDC:68387-340-60	60 in 1 BOTTLE, PLASTIC		
4	NDC:68387-340-90	90 in 1 BOTTLE, PLASTIC		
5	NDC:68387-340-24	240 in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA085159	07/25/2007	

**Labeler** - Keltman Pharmaceuticals Inc. (362861077)

## Establishment

Name	Address	ID/FEI	Business Operations
Sandhills Packaging		825138717	repack

Revised: 8/2010

Keltman Pharmaceuticals Inc.