

**METHOCARBAMOL - methocarbamol tablet, coated**  
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**Burel Pharmaceuticals, Inc.**

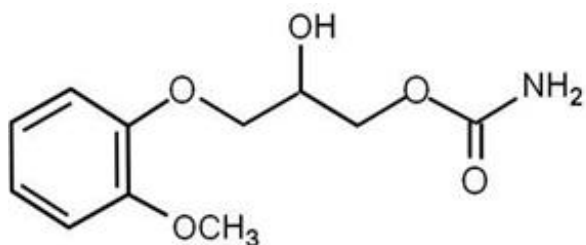
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**Methocarbamol Tablets, USP**

**Rx Only**

**DESCRIPTION**

Methocarbamol tablet, 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 1,2-Propanediol,3-(2-methoxyphenoxy)-,1-Carbamate,(±)-(or) (±)-3-(o-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 241.24g/mol. The structural formula is shown below.



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

Methocarbamol tablets, USP are available as 500 mg and 750 mg tablets for oral administration.

Methocarbamol tablets, USP 500 mg are light orange colored, round shaped film coated tablets debossed with "G" above the score line on one side and "500" on other side.

Methocarbamol tablets, USP 750 mg are light orange colored, caplet shaped film coated tablets debossed with "G" on one side and "750" on other side.

Methocarbamol tablets, USP 500 mg and 750 mg contain the following inactive ingredients: colloidal silicon dioxide, maize starch, povidone, sodium lauryl sulfate, sodium starch glycolate, and stearic acid.

The tablets are coated with Aquarius Prime which contains FD&C yellow 6, hydroxypropylcellulose, hypromellose, polysorbate 80, propylene glycol, and 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).

### *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, USP 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 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 tablet 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 Granules Pharmaceutical Inc., at 1-877-770-3183 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://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**

Methocarbamol Tablets, USP 500 mg – Adults:

Initial dosage: 3 tablets 4 times daily

Maintenance dosage: 2 tablets 4 times daily

Methocarbamol Tablets, USP 750 mg – Adults:

Initial dosage: 2 tablets 4 times daily

Maintenance dosage: 1 tablet every 4 hours or 2 tablets 3 times daily

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 light orange colored, round shaped film coated tablets debossed with "G" above the score line on one side and "500" on other side.

They are supplied as follows

Bottles of 100 tablets NDC 35573-413-02

Bottles of 500 tablets NDC 35573-413-04

Methocarbamol tablets, USP 750 mg are light orange colored, caplet shaped film coated tablets debossed with "G" on one side and "750" on other side.

Bottles of 100 tablets NDC 35573-414-02

Bottles of 500 tablets NDC 35573-414-04

**Store between 20°C and 25°C (68°F and 77°F)**

**[see USP Controlled Room Temperature].**

Dispense in tight container.

Manufactured for:

**Burel Pharmaceuticals, Inc.**

Brandon, MS 39042 USA

Manufactured by:

**Granules India Limited**

Hyderabad - 500 081, India.

MADE IN INDIA

M.L.No.: 37/RR/AP/2003/F/R

Revision Date: December 2020

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 35573-414-04

 **burelpharma**

**Methocarbamol  
Tablets, USP**

**750 mg**

**500 Tablets** **Rx Only**

**Each Film-Coated Tablet Contains:**  
Methocarbamol USP, 750 mg  
**Dosage:** See package insert for full  
prescribing information.  
**Store between 20°C and 25°C (68°F and 77°F)**  
**[See USP Controlled Room Temperature].**  
Dispense in tight container.  
**Keep this and all drugs out of reach of  
children.**  
Manufactured for:  
**Burel Pharmaceuticals, Inc.**  
Brandon, MS 39042 USA  
Manufactured by: **Granules India Limited**  
Hyderabad-500 081, India  
MADE IN INDIA

  
3 35573 414 04 7

**Un Varnish  
Area  
45x25 mm**

R12/20  
20000003041  
M. L. No.: 37/RR/AP/2003/F/R





NDC 35573-414-02

# Methocarbamol Tablets, USP

**750 mg**

100 Tablets

Rx Only

**Each Film-Coated Tablet Contains:**  
 Methocarbamol USP, 750 mg  
**Dosage:** See package insert for full prescribing information.  
 Store between 20°C and 25°C (68°F and 77°F) [See USP Controlled Room Temperature]. Dispense in tight container. Keep this and all drugs out of reach of children.  
 Manufactured for:  
**Burel Pharmaceuticals, Inc.**  
 Brandon, MS 39042 USA  
 Manufactured by: **Granules India Limited**  
 Hyderabad-500 081, India.  
**MADE IN INDIA**



3 35573 41402 3

Un Varnish Area  
45x23 mm

R12/20  
20000003040  
M, L, No.: 37/RR/AP/2003/F/R



NDC 35573-413-04

# Methocarbamol Tablets, USP

**500 mg**

500 Tablets

Rx Only

**Each Film-Coated Tablet Contains:**  
 Methocarbamol USP, 500 mg  
**Dosage:** See package insert for full prescribing information.  
 Store between 20°C and 25°C (68°F and 77°F) [See USP Controlled Room Temperature]. Dispense in tight container. Keep this and all drugs out of reach of children.  
 Manufactured for:  
**Burel Pharmaceuticals, Inc.**  
 Brandon, MS 39042 USA  
 Manufactured by: **Granules India Limited**  
 Hyderabad-500 081, India  
**MADE IN INDIA**



3 35573 413 04 0

Un Varnish Area  
45x25 mm

R12/20  
20000003039  
M, L, No.: 37/RR/AP/2003/F/R



NDC 35573-413-02

# Methocarbamol Tablets, USP

**500 mg**

100 Tablets

Rx Only

**Each Film-Coated Tablet Contains:**  
 Methocarbamol USP, 500 mg  
**Dosage:** See package insert for full prescribing information.  
 Store between 20°C and 25°C (68°F and 77°F) [See USP Controlled Room Temperature]. Dispense in tight container. Keep this and all drugs out of reach of children.  
 Manufactured for:  
**Burel Pharmaceuticals, Inc.**  
 Brandon, MS 39042 USA  
 Manufactured by: **Granules India Limited**  
 Hyderabad-500 081, India  
**MADE IN INDIA**



3 35573 41302 6

Un Varnish Area  
45x23 mm

R12/20  
20000003038  
M, L, No.: 37/RR/AP/2003/F/R



## METHOCARBAMOL

methocarbamol tablet, coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:35573-414
<b>Route of Administration</b>	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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	G;750
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35573-414-02	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2019	
2	NDC:35573-414-04	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209312	09/30/2019	

## METHOCARBAMOL

methocarbamol tablet, coated

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:35573-413
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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

**Product Characteristics**

Color	orange	Score	2 pieces
Shape	ROUND	Size	13mm
Flavor		Imprint Code	G;500
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35573-413-02	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2019	
2	NDC:35573-413-04	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209312	09/30/2019	

**Labeler** - Burel Pharmaceuticals, Inc. (609436204)**Establishment**

Name	Address	ID/FEI	Business Operations
Granules India Ltd		918609236	analysis(35573-413, 35573-414) , label(35573-413, 35573-414) , manufacture(35573-413, 35573-414) , pack(35573-413, 35573-414)

Revised: 2/2023

Burel Pharmaceuticals, Inc.