METHOCARBAMOL- methocarbamol tablet, film coated
Bayshore Pharmaceuticals LLC

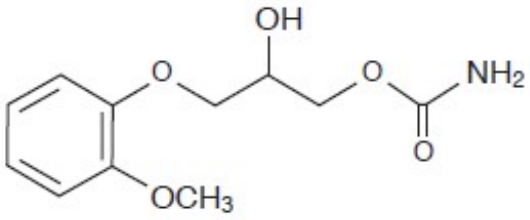
Methocarbamol Tablets USP, 500 mg and 750 mg

(Methocarbamol USP)
Rx Only

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 Tablets USP, 500 mg is available as a light orange colored, round, film-coated tablets, engraved with 'B134' on one side and scored on the other side, containing 500 mg of methocarbamol, USP for oral administration. The inactive ingredients present are corn starch, low substituted hydroxypropyl cellulose, hydroxyprolyl cellulose, sodium starch glycolate, povidone, sodium lauryl sulfate, colloidal silicon dioxide, stearic acid, magnesium stearate, and purified water. Methocarbamol Tablets USP, 500 mg contains Opadry 13H530000 (Orange) (hypromellose, titanium dioxide, propylene glycol, FD&C yellow #6/Sunset Yellow FCF Aluminum Lake, polysorbate 20) as coating material.

Methocarbamol Tablets USP, 750 mg is available as an orange colored, capsule shaped, film coated tablets, engraved with 'B135' on one side and plain on the other side, containing 750 mg of methocarbamol, USP for oral administration. It contains Opadry 13H530001 (Orange) as coating material. The inactive ingredients present are corn starch, low substituted hydroxypropyl cellulose, hydroxyprolyl cellulose, sodium starch glycolate, povidone, sodium lauryl sulfate, colloidal silicon dioxide, stearic acid, magnesium stearate, and purified water. Methocarbamol Tablets USP, 750 mg contain Opadry 13H530001 (Orange) (hypromellose, titanium dioxide, propylene glycol, D&C Yellow #10 Aluminum Lake, FD&C yellow #6/Sunset Yellow FCC Aluminum Lake, polysorbate 20) as coating material.

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 (± SD) elimination half-life of methocarbamol in elderly healthy volunteers (mean (± SD) age, 69 (± 4) years) was slightly prolonged compared to a younger (mean (± SD) age, 53.3 (± 8.8) years), healthy population (1.5 (± 0.4) hours versus 1.1 (±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 (± SD) elimination half-life in these two groups was similar: 1.2 (± 0.6) versus 1.1 (±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 (± SD) elimination half-life in the cirrhotic patients and the normal subjects was 3.38 (± 1.62) hours and 1.11 (± 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, 500 mg and 750 mg 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 USP, 500 mg and 750 mg 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 USP, 500 mg or 750 mg should be cautioned about combined effects with alcohol and other CNS depressants.

Safe use of Methocarbamol Tablets USP, 500 mg and 750 mg 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 USP, 500 mg and 750 mg 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 USP, 500 mg and 750 mg should be given to a pregnant woman only if clearly needed.

Safe use Methocarbamol Tablets USP, 500 mg and 750 mg 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 USP, 500 mg and 750 mg 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 USP, 500 mg or 750 mg is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Methocarbamol Tablets USP, 500 mg and 750 mg 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 Tablets USP, 500 mg – Adults:
Initial dosage: 3 tablets q.i.d.
Maintenance dosage: 2 tablets q.i.d.

Methocarbamol Tablets USP, 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 are light orange colored, round, film-coated tablets, engraved with 'B134' on one side and scored on the other side. They are supplied as follows:

Bottles of 100 NDC 76385-123-01
Bottles of 500 NDC 76385-123-50

Methocarbamol Tablets USP, 750 mg are orange colored, capsule shaped, film coated tablets, engraved with 'B135' on one side and plain on the other side. They are supplied as follows:

Bottles of 100 NDC 76385-124-01

Bottles of 500 NDC 76385-124-50

Store at controlled room temperature, between 20°C and 25°C (68°F and 77°F). Dispense in tight container.

Manufactured for
Beximco Pharmaceuticals USA Inc.
4110 Regal Oaks Drive, P.O. Box 1060 Suwanee, GA 30024, USA

Manufactured by
BEXIMCO PHARMACEUTICALS LTD.

126, Kathaldia, Tongi, Gazipur, 1711, Bangladesh

Distributed by:

Bayshore Pharmaceuticals LLC
Short Hills, NJ 07078

Last revised on 12/2017
5001397 111217

500 mg 100 Count Bottle Label

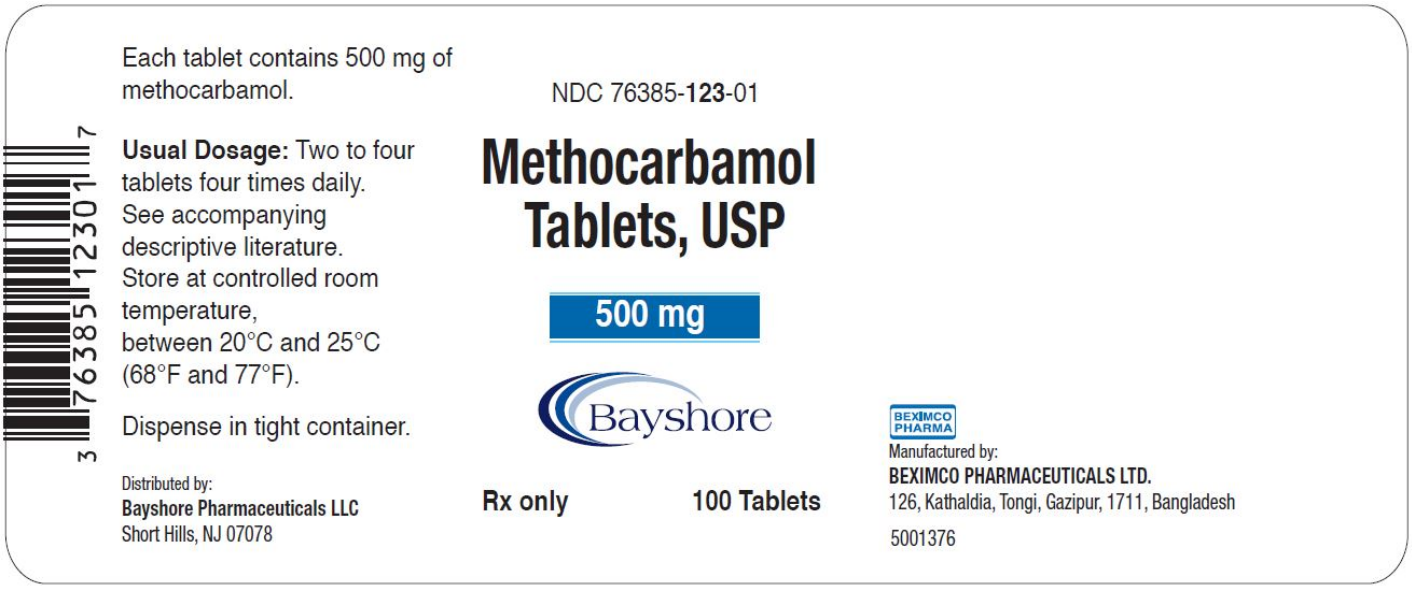
NDC 76385-123-01

Methocarbamol Tablets USP, 500 mg

(Methocarbamol USP)

500 mg

Rx Only 100 tablets



750mg 100 Count Bottle Label

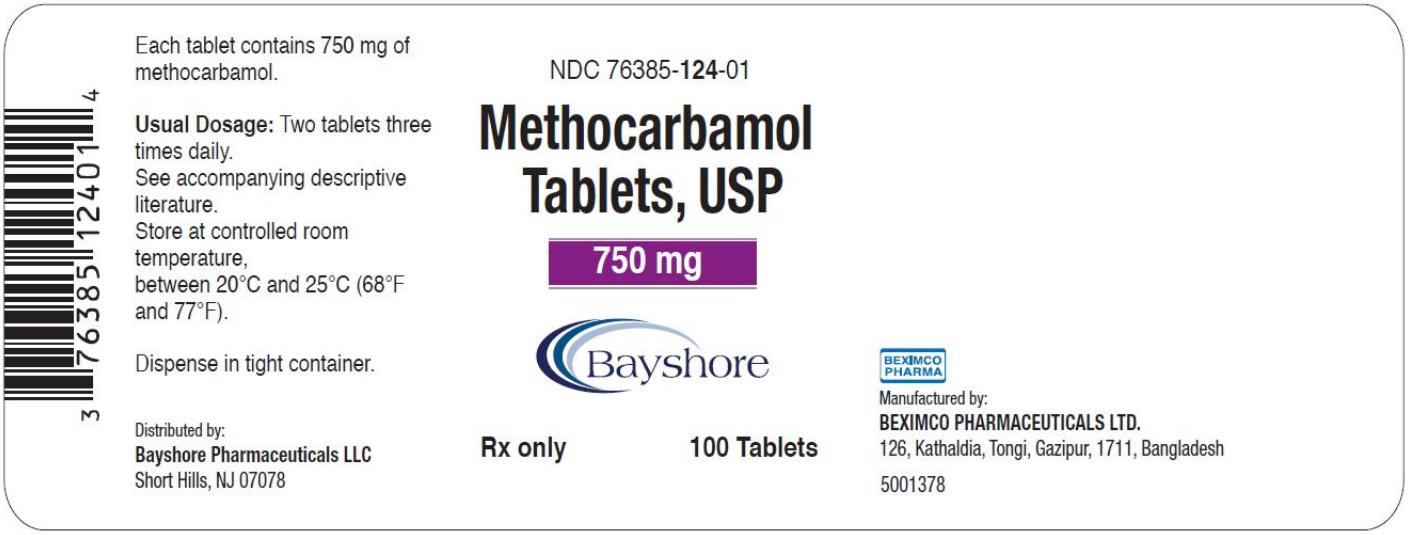
NDC 76385-124-01

Methocarbamol Tablets USP, 750 mg

(Methocarbamol USP)

750 mg

Rx Only 100 tablets



METHOCARBAMOL

methocarbamol tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:76385-123
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**
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Product Characteristics			
Color	orange (light orange)	**Score**	2 pieces

Shape	ROUND	**Size**	13mm
Flavor		**Imprint Code**	B134
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76385-123-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2018	
2	NDC:76385-123-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208507	01/15/2018	

METHOCARBAMOL

methocarbamol tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:76385-124
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
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Product Characteristics

Color	orange (orange)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	B135
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76385-124-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2018	
2	NDC:76385-124-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208507	01/15/2018	

Labeler - Bayshore Pharmaceuticals LLC (968737416)

Registrant - Beximco Pharmaceuticals USA Inc. (962288143)

Establishment

Name	Address	ID/FEI	Business Operations
Beximco Pharmaceuticals Ltd		731579053	manufacture(76385-123, 76385-124)

Revised: 1/2024 Bayshore Pharmaceuticals LLC