

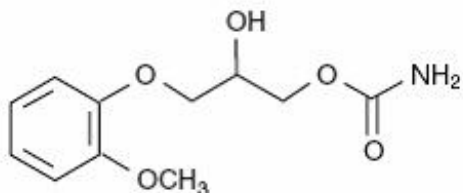
ROBAXIN - methocarbamol tablet, film coated
STAT RX USA LLC

Rx Only

DESCRIPTION

robaxin[®]/robaxin[®]-750 (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 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.

robaxin[®] is available as a light orange, round, film-coated tablet containing 500 mg of methocarbamol, USP for oral administration. The inactive ingredients present are corn starch, FD and C Yellow 6, hydroxypropyl cellulose, hypromellose, magnesium stearate, polysorbate 20, povidone, propylene glycol, saccharin sodium, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide.

robaxin[®]-750 is available as an orange capsule-shaped, film-coated tablet containing 750 mg of methocarbamol, USP for oral administration. In addition to the inactive ingredients present in robaxin[®], robaxin[®]-750 also contains D and C Yellow 10.

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

robaxin[®] and robaxin[®]-750 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

robaxin[®] and robaxin[®]-750 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 robaxin[®] or robaxin[®]-750 should be cautioned about combined effects with alcohol and other CNS depressants.

Safe use of robaxin[®] and robaxin[®]-750 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, robaxin[®] and robaxin[®]-750 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. robaxin[®] and robaxin[®]-750 should be given to a pregnant woman only if clearly needed.

Safe use of robaxin[®] and robaxin[®]-750 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, robaxin[®] and robaxin[®]-750 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 robaxin[®] or robaxin[®]-750 is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of robaxin[®] and robaxin[®]-750 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

robaxin[®] (methocarbamol), 500 mg – Adults:

Initial dosage: 3 tablets q.i.d.

Maintenance dosage: 2 tablets q.i.d.

robaxin[®]-750 (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

robaxin[®] (methocarbamol tablets, USP)

500 mg tablets are light orange, round, film-coated tablets engraved with ROBAXIN 500 on the unscored side and SP above the score on the other side. They are supplied as follows:

Bottles of 100

NDC 0091-7429-63

robaxin[®]-750 (methocarbamol tablets, USP)

750 mg tablets are orange, capsule-shaped, film-coated tablets engraved with ROBAXIN 750 on one side and SP on the other. They are supplied as follows:

Bottles of 100

NDC 0091-7449-63

Bottles of 500

NDC 0091-7449-70

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

Dispense in tight container.

Manufactured for:
 SCHWARZ PHARMA, LLC
 a subsidiary of UCB, Inc.
 Smyrna, GA 30080

Printed in USA

Rev. 1E 09/2009

PACKAGE LABEL - ROBAXIN 750 MG TABLET

Packaged and distributed by: **STAT R USA** Gainesville, GA 30501

Robaxin
750mg **120 Tabs**

Generic For:
NDC 16590-981-72 Prod# 981-72
 Lot# SAMPLE
 Each Tablet Contains: Methocarbamol USP
 750mg

Mfg By: Schwarz Pharma, LLC
 Smyrna, GA 30080 NDC 0091-7449-63
 Mfg Lot: 0993601 MD 6/1/2011 SAMPLE
 Discard After: 07/13

RX ONLY-KEEP OUT OF REACH OF CHILDREN

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.
May cause DROWSINESS. ALCOHOL may INTENSIFY this effect. Use care when operating dangerous machinery. \$ May cause drowsiness or dizziness.

0 \$

ROBAXIN			
methocarbamol tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:16590-981(NDC:0091-7449)
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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL (Capsule-shaped)	Size	19mm
Flavor		Imprint Code	Robaxin;750;SP
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16590-981-30	30 in 1 BOTTLE		
2	NDC:16590-981-60	60 in 1 BOTTLE		
3	NDC:16590-981-90	90 in 1 BOTTLE		
4	NDC:16590-981-72	120 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA011011	01/20/2003	

Labeler - STAT RX USA LLC (786036330)

Establishment

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	relabel, repack