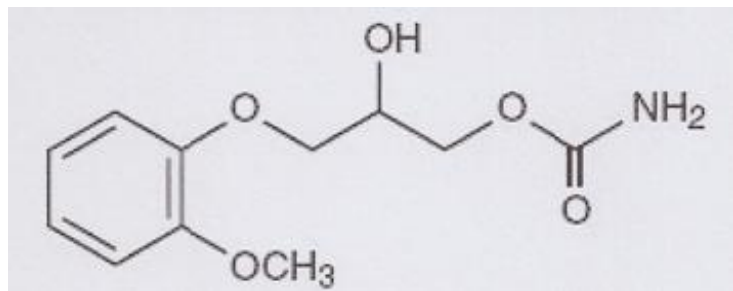


METHOCARBAMOL - methocarbamol tablet
REMEDYREPACK INC.

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 C₁₁H₁₅NO₅. 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 (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 (hours) versus 1.1 (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 (elimination half-life in these two groups was similar: 1.2 (versus 1.1 (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 (elimination half-life in the cirrhotic patients and the normal subjects was 3.38 (hours and 1.11 (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 & 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 WARNINGSandPRECAUTIONSfor 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**).

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.

Nursing Mothers

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 Pharmaceutical 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 & 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 Tablets; Debossed "West-ward 290" on one side and Scored on the other side.

Bottles of 100 tablets

Bottles of 500 tablets

Bottles of 1000 tablets

Unit Dose Box of 100 tablets

Methocarbamol Tablets 750 mg: White, Capsule Shaped Tablets; Debossed "WEST-WARD 292" on one side and Scored on the other side.

Bottles of 100 tablets

Bottles of 500 tablets

Bottles of 1000 tablets

Unit Dose Box of 100 tablets

STORAGE AND HANDLING

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.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL SECTION

DRUG: METHOCARBAMOL

GENERIC: METHOCARBAMOL

DOSAGE: TABLET

ADMINISTRATION: ORAL

NDC: 24236-332-03

STRENGTH:500 mg

COLOR: white

SHAPE: ROUND

SCORE: Two even pieces

SIZE: 20 mm

IMPRINT: 30

QTY: 30

METHOCARBAMOL**500 MG TAB
QTY:00020****NDC#: 24236-0332-03 INT:MS ID#:290****EXPIRES: 10/2013****LOT#: DP1012012345****COL: white****SHP: round****DIST: WESTWARD PHARMA EATONTOWN NJ 07724****MFG: WESTWARD PHARMA EATONTOWN NJ 07724****A. Caution Federal law prohibits transfer of this drug to any person other than for whom it was prescribed.****B. Store at a temperature between 15 degree C and 30 degree C (59 degree F and 86 degree F) {see USP}****C. Re-packaged by: RemedyRepack Inc. 655 Kolter Dr., Indiana, PA 15701, 1-724-465-8762****METHOCARBAMOL**

methocarbamol tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:24236-332(NDC:0143-1290)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHOCARBAMOL (METHOCARBAMOL)	METHOCARBAMOL	500 mg

Inactive Ingredients

Ingredient Name	Strength
METHYLCELLULOSE (100 MPA.S)	
LACTOSE MONOHYDRATE	
STARCH, CORN	
SILICON DIOXIDE	
MAGNESIUM STEARATE	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24236-332-03	20 in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA085159	01/19/2013	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 1/2013

REMEDYREPACK INC.