ROBAXIN- methocarbamol tablet, film coated
DIRECT RX

METHOCARBAMOL

Methocarbamol Tablets USP, 500 mg and 750 mg, 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. Methocarbamol tablet, 500 mg is available as an orange, film coated, round convex tablet containing 500 mg of methocarbamol, USP for oral administration. The inactive ingredients present are microcrystalline cellulose, croscarmellose sodium, FD&C Yellow 6 Aluminum Lake, hydroxypropyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, triacetin, titanium dioxide. Methocarbamol tablet, 750 mg is available as a yellow, film coated, modified capsule shaped tablet containing 750 mg of methocarbamol, USP for oral administration. The inactive ingredients present are microcrystalline cellulose, croscarmellose sodium, iron oxide yellow, iron oxide red, hydroxypropyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, triacetin, titanium dioxide.

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.

Methocarbamol is 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.

Methocarbamol is contraindicated in patients hypersensitive to methocarbamol or to any of the tablet components.

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 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 AlertnessMethocarbamol 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.

Information for PatientsPatients 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 InteractionsSee 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 InteractionsMethocarbamol 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 FertilityLong-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.PregnancyTeratogenic EffectsPregnancy Category CAnimal 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 should be given to a pregnant woman only if clearly needed.Safe use of methocarbamol 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 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 MothersMethocarbamol 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 is administered to a nursing woman.Pediatric UseSafety and effectiveness of methocarbamol in pediatric patients below the age of 16 have not been established.

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

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.

Methocarbamol, 500 mg — Adults: Initial dosage: 3 tablets q.i.d.

Maintenance dosage: 2 tablets q.i.d.

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.

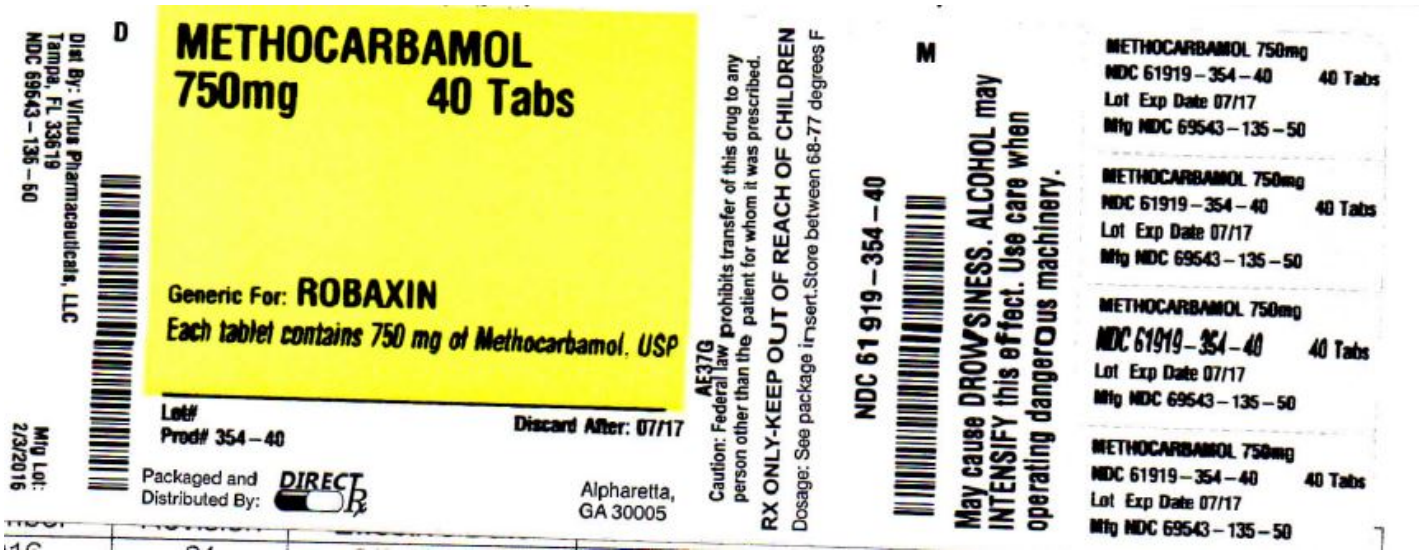
HOW SUPPLIED

Methocarbamol Tablets USP, 500 mg — Orange, film coated, round convex tablets with one side debossed 'AP212', the other side bisected. Available in bottles of 100 and 500.

Methocarbamol Tablets USP, 750 mg — Yellow, film coated, modified capsule shaped tablets; one side debossed 'AP211' and other side blank. Available in bottles of 100 and 500.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight container.



ROBAXIN

methocarbamol tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-354(NDC:69543-135)
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**
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
TRIACETIN (UNII: XHX3C3X673)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	yellow	**Score**	score with uneven pieces
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	AP211
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-354-40	1 in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200958	02/03/2016	

Labeler - DIRECT RX (079254320)

Registrant - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-354)

Revised: 5/2016 DIRECT RX