METHOCARBAMOL- methocarbamol tablet, coated
METHOCARBAMOL- methocarbamol tablet
DIRECT RX

METHOCARBAMOL 750mg 120TABS

DESCRIPTION

Methocarbamol tablets, USP, a carbamate derivative of guaifenesin, are a central nervous system (CNS) depressant with sedative and musculoskeletal relaxant properties.

The chemical name of methocarbamol is 3-(2-meth-oxyphenoxy)-1,2-propanediol 1-carbamate and has the empirical formula C11H15NO5. Its molecular weight is 241.24. The structural formula is shown below.

[Methocarbamol Chemical Structure]

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 are available as 500 mg and 750 mg tablets for oral administration. Methocarbamol tablets, USP 500 mg and 750 mg contain the following inactive ingredients: povidone, sodium starch glycolate and magnesium stearate.

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.

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, USP 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 should be cautioned about combined effects with alcohol and other CNS depressants.

Safe use of Methocarbamol tablets, USP 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 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 should be given to a pregnant woman only if clearly needed.

Safe use of Methocarbamol tablets, USP 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 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 are administered to a nursing woman.

Pediatric use

Safety and effectiveness of Methocarbamol tablets, USP 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.

STORAGE

Store at controlled room temperature, between 20°C and 25°C (68°F and 77°F).
[see USP Controlled Room Temperature].
Dispense in tight container.

Methocarbamol tablets, USP 500 mg are white to off white, capsule shaped, tablets debossed with ‘H’ on scored side and ‘114’ on unscored side .

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

Store between 20ºC and 25ºC (68ºF and 77º F)

[see USP Controlled Room Temperature].

Dispense in tight container.

Manufactured for:

Granules USA, Inc.

Parsippany, NJ 07054

Toll-free: 1-877-770-3183

Manufactured by:

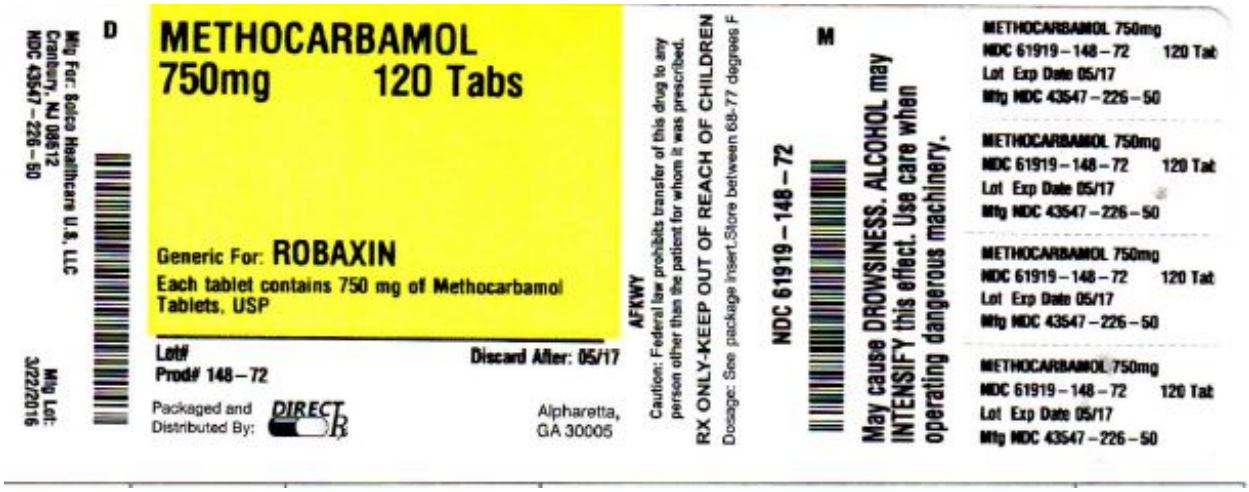
Granules India Limited

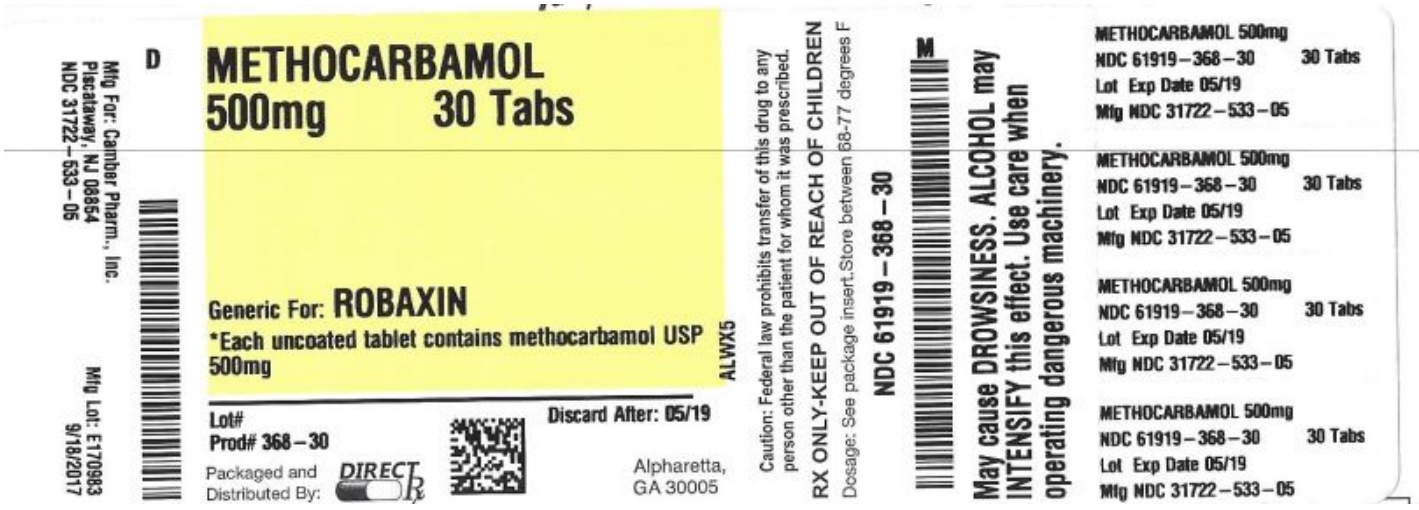
Hyderabad-500 081

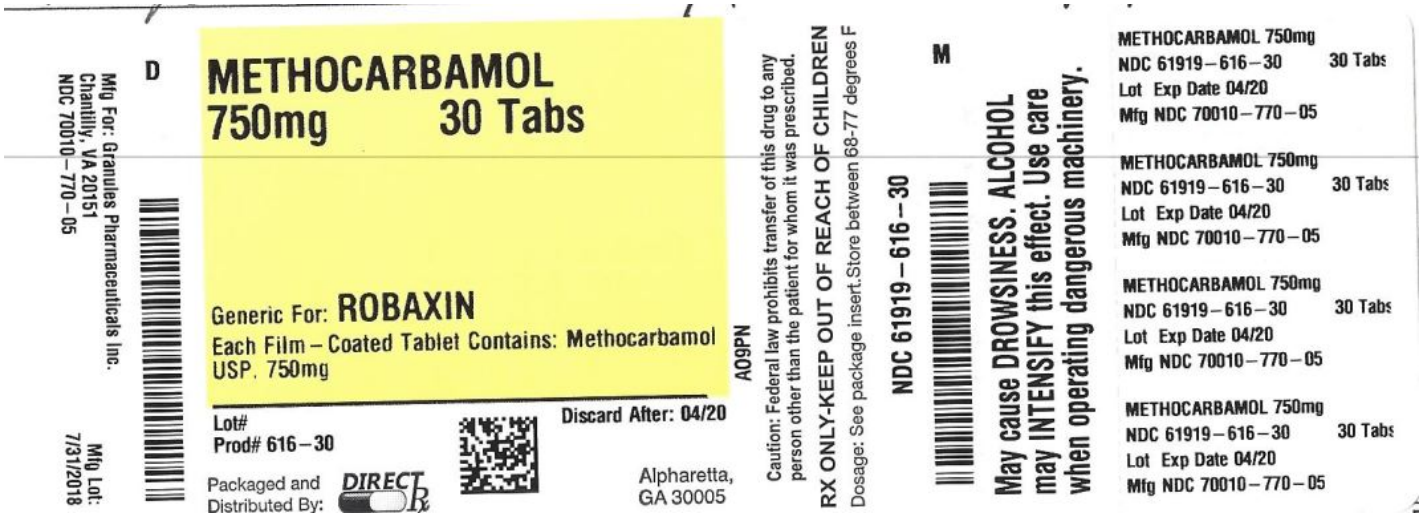
Made in India

Issued: January 2017

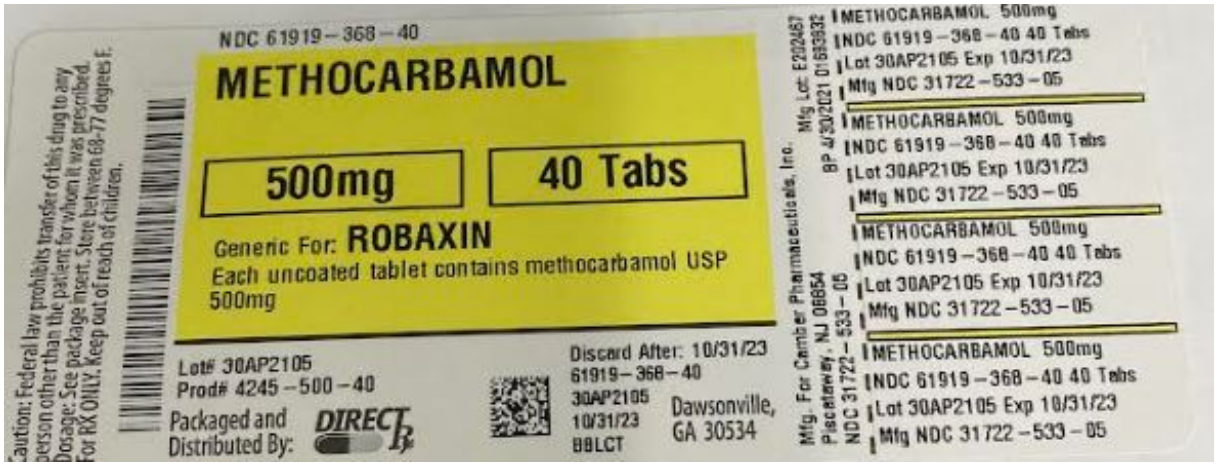
PACKAGE LABEL 750MG

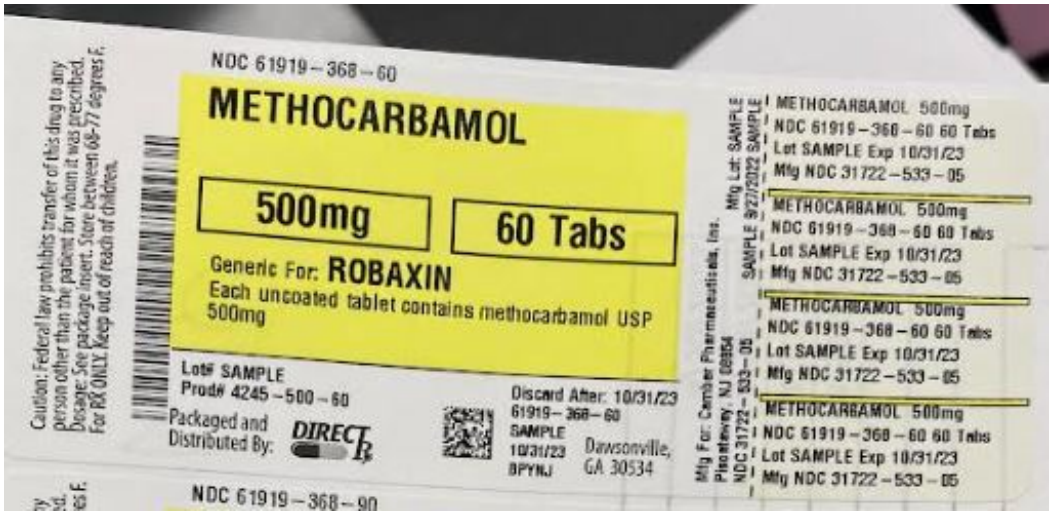


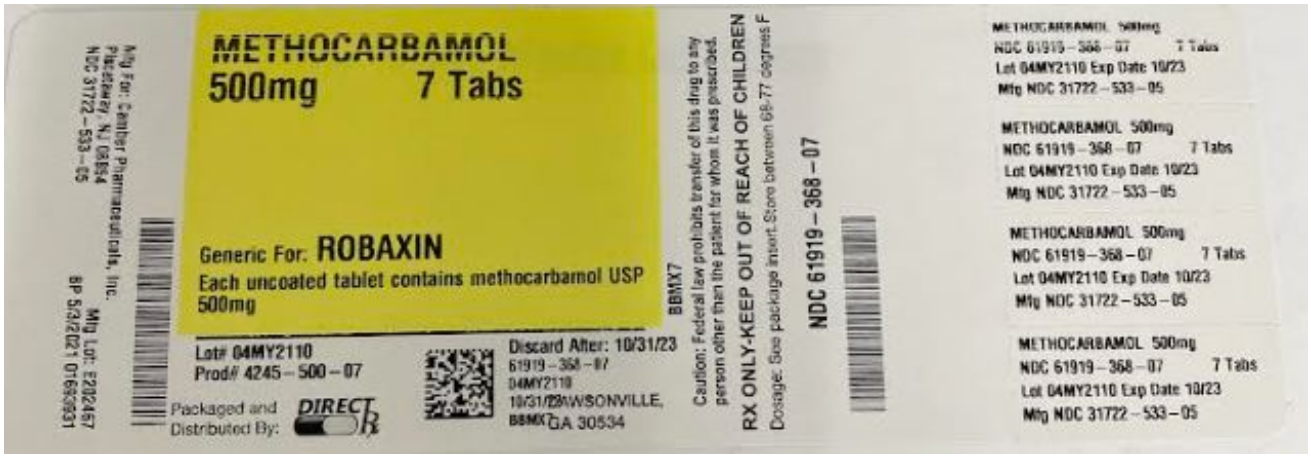



D
METHOCARBAMOL
750mg 30 Tabs
Generic For: ROBAXIN
Each Film – Coated Tablet Contains: Methocarbamol USP, 750mg
Lot#
Prod# 616 – 30
Discard After: 04/20
Packaged and Distributed By: DIRECT Rx
Alpharetta, GA 30005
Mfg For: Granules Pharmaceuticals Inc.
Chantilly, VA 20151
NDC 70010 – 770 – 05
Mfg Lot: 7/13/2018
A09PN
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.
RX ONLY-KEEP OUT OF REACH OF CHILDREN
Dosage: See package insert. Store between 68-77 degrees F
NDC 61919 – 616 – 30
M
May cause DROWSINESS. ALCOHOL may INTENSIFY this effect. Use care when operating dangerous machinery.
METHOCARBAMOL 750mg
NDC 61919 – 616 – 30 30 Tabs
Lot Exp Date 04/20
Mfg NDC 70010 – 770 – 05


NDC 61919 – 616 – 60
METHOCARBAMOL
750mg 60 Tabs
Generic For: ROBAXIN
Each Film – Coated Tablet Contains: Methocarbamol USP, 750mg
Lot# SAMPLE
Prod# 4245 – 750 – 60
Discard After: 12/31/24
61919 – 616 – 60
SAMPLE
12/31/24
80AZF
Packaged and Distributed By: DIRECT Rx
Dawsonville, GA 30534
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed. Dosage: See package insert. Store between 68-77 degrees F. For RX ONLY. Keep out of reach of children.
Mfg For: Granules Pharmaceuticals Inc.
Chantilly, VA 20151
NDC 70010 – 770 – 05
Mfg Lot: SAMPLE
10/7/2022 SAMPLE
METHOCARBAMOL 750mg
NDC 61919 – 616 – 60 60 Tabs
Lot SAMPLE Exp 12/31/24
Mfg NDC 70010 – 770 – 05


NDC 61919 – 368 – 40
METHOCARBAMOL
500mg 40 Tabs
Generic For: ROBAXIN
Each uncoated tablet contains methocarbamol USP 500mg
Lot# 30AP2105
Prod# 4245 – 500 – 40
Discard After: 10/31/23
61919 – 368 – 40
30AP2105
10/31/23
88LCT
Packaged and Distributed By: DIRECT Rx
Dawsonville, GA 30534
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed. Dosage: See package insert. Store between 68-77 degrees F. For RX ONLY. Keep out of reach of children.
Mfg. For: Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854
NDC 31722 – 533 – 05
Mfg Lot: E202487
BP 4/30/2021 D1693932
METHOCARBAMOL 500mg
NDC 61919 – 368 – 40 40 Tabs
Lot 30AP2105 Exp 10/31/23
Mfg NDC 31722 – 533 – 05





METHOCARBAMOL

methocarbamol tablet, coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-616(NDC:70010-770)
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
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

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:61919-616-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2019	
2	NDC:61919-616-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209312	04/18/2019	

METHOCARBAMOL

methocarbamol tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-148(NDC:43547-226)
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**
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	white (White to off White)	**Score**	no score
Shape	CAPSULE (Capsule Shaped)	**Size**	18mm
Flavor		**Imprint Code**	S226
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-148-72	120 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA086988	03/22/2016	

METHOCARBAMOL

methocarbamol tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-368(NDC:31722-533)
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
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE K90 (UNII: RDH86HJV5Z)	

Product Characteristics

Color	white (White to Offwhite)	**Score**	2 pieces
Shape	OVAL (Capsule shaped)	**Size**	15mm
Flavor		**Imprint Code**	114;H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-368-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2019	
2	NDC:61919-368-40	40 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2019	
3	NDC:61919-368-07	7 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2019	
4	NDC:61919-368-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2019	
5	NDC:61919-368-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090200	04/18/2019	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-148, 61919-368) , relabel(61919-616)