LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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January 3, 2006

**OVERNIGHT COURIER 1/3/06**

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Citizen Petition**

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act, and in accordance with 21 CFR 10.30 on behalf of a client requesting the Commissioner of the Food and Drug Administration to declare that the drug product, Methocarbamol Tablets USP, 1000 mg, is suitable for consideration in an abbreviated new drug application (ANDA).

## A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Methocarbamol Tablets USP, 1000 mg, is suitable for submission as an ANDA. The listed reference drug product (RLD), upon which this petition is based, is Robaxin-750® Tablets (methocarbamol), 750 mg, NDA 11-011 currently held by Schwarz Pharma. In addition, the petitioner also refers to the approved 500 mg strength of Methocarbamol Tablets listed (and also designated as an RLD) in the Orange Book in support of this petition. Therefore, the petitioner seeks a change in strength (from 750 mg to 1000 mg), from that of the listed drug product.

## B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The Reference-Listed Drug (RLD), Robaxin-750® Tablets by Schwarz Pharma is a tablet product containing 750 mg of methocarbamol. See product listing for NDA 11-011 from the electronic Orange Book also known as the *Approved Drug Products with Therapeutic Equivalence Evaluations*, accessed January 3, 2006, which also lists the approval of the 500 mg strength (Attachment 1). The proposed drug product also represents a tablet dosage form, but containing 1000 mg of methocarbamol. The petition is thus seeking a change in strength (from 750 mg to 1000 mg), from that of the RLD. Please note that the proposed change in strength

represents a dosage strength that is consistent with the dosing recommendations of the RLD's approved labeling.

The acceptability of the proposed 1000 mg strength is clearly contemplated in the labeling of the approved 750 mg RLD drug and the approved 500 mg tablet product. The current dosing instructions in the approved labeling of the RLD are as follows:

> The initial dose is 3 (500 mg) tablets four times a day. The maintenance dose is 2 (500 mg) tablets four times a day. The initial dose of the 750 mg tablet is 2 (750 mg) tablets four times a day with maintenance being 1 (750 mg) tablet every 4 hours or 2 (750 mg) tablets three times a day.
>
> 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.

Both the labeling of the approved 500 mg methocarbamol and the RLD's 750 mg labeling clearly describe a dose of 1000 mg or higher. The proposed product also represents a tablet that can attain several of the total daily dosages recommended in the approved labeling of the RLD, without exceeding the single maximum dose of 1500 mg permitted. The 1000 mg proposed product represents the natural maintenance regimen contemplated from that of the 500 mg approved product and provides the prescribing physician the flexibility in selecting and prescribing the appropriate dose for a specific patient based on their response. From the patient's perspective, the 1000 mg tablet will provide a more convenient dosage strength tablet that will not involve the need to take multiple tablets to achieve the desired 1000 mg prescribed dosage level, if deemed appropriate by the physician for the individual patient.

There are no proposed changes in labeling with the exception of the obvious changes in strength sought in this petition. The uses, indications, warnings and directions for use will remain the same as that of the RLD. Draft labeling for the proposed product is included in Attachment 2. The 750 mg RLD's (also containing dosing recommendations for the 500 mg tablet) approved labeling are provided in Attachment 3.

Therefore, the petitioner's request for the Commissioner to find that a change in strength from 750 mg to 1000 mg, for Methocarbamol Tablets USP should raise no questions of safety or effectiveness, and the Agency should approve the petition.

## C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

## D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the Agency.

## E. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

Robert Pollock PK

Robert W. Pollock
Senior Vice President

RWP/pk

Attachments:
1. Approved Drug Products with Therapeutic Equivalence Evaluations, Electronic Orange Book listing accessed January 3, 2006
2. Draft Insert Labeling Proposed for Methocarbamol 1000 mg Tablets, USP
3. Labeling for Robaxin-750®, 750 mg Tablets, including the 500 mg Strength

cc: Arianne Camphire (OGD)

*A43P6003*

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Westbury, NY 11590

# ATTACHMENT 1

**Search results from the "OB_Rx" table for query on "011011."**

| | |
|---|---|
| Active Ingredient: | METHOCARBAMOL |
| Dosage Form;Route: | TABLET; ORAL |
| Proprietary Name: | ROBAXIN |
| Applicant: | SCHWARZ PHARMA |
| Strength: | 500MG |
| Application Number: | 011011 |
| Product Number: | 004 |
| Approval Date: | Approved Prior to Jan 1, 1982 |
| Reference Listed Drug | Yes |
| RX/OTC/DISCN: | RX |
| TE Code: | **AA** |
| Patent and Exclusivity Info for this product: | View |

| | |
|---|---|
| Active Ingredient: | METHOCARBAMOL |
| Dosage Form;Route: | TABLET; ORAL |
| Proprietary Name: | ROBAXIN-750 |
| Applicant: | SCHWARZ PHARMA |
| Strength: | 750MG |
| Application Number: | 011011 |
| Product Number: | 006 |
| Approval Date: | Approved Prior to Jan 1, 1982 |
| Reference Listed Drug | Yes |
| RX/OTC/DISCN: | RX |
| TE Code: | **AA** |
| Patent and Exclusivity Info for this product: | View |

Return to Electronic Orange Book Home Page

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through November, 2005
Patent and Generic Drug Product Data Last Updated: December 30, 2005

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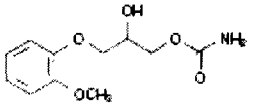
Westbury, NY 11590

# ATTACHMENT 2

## Methocarbamol 1gm tablets,USP

Methocarbamol 1gm tablets, 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 1gm tablets are available as a light orange, round, filmcoated tablet containing 500 mg of methocarbamol, USP for oral administration. The inactive ingredients present are corn starch, FD&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.

Methocarbamol 1gm tablets are available as an orange capsuleshaped, film-coated tablet containing 750 mg of methocarbamol, USP for oral administration. In addition to the inactive ingredients present in methocarbamol 1gm tablets, methocarbamol 1gm tablets also contains D&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 (± 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 renallyimpaired 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 1gm 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 1gm 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 1gm tablets should be cautioned about combined effects with alcohol and other CNS depressants.

Safe use of methocarbamol 1gm 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 1gm 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 **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 1gm tablets should be given to a pregnant woman only if clearly needed. Safe use of methocarbamol 1gm 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 1gm 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**).

### 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 1gm tablets is administered to a nursing woman.

### Pediatric Use

Safety and effectiveness of methocarbamol 1gm 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

## 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 1gm tablets – Adults:
Initial dosage: 1½ tablets q.i.d.
Maintenance dosage: 1 tablets q.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 1gm tablets are [color to be determined], scored, film-coated tablets. They are supplied as follows:

[TBD]

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

LACHMAN CONSULTANT SERVICES, INC.
Westbury, NY 11590

# ATTACHMENT 3

4449D

**robaxin®**

**robaxin®-750**

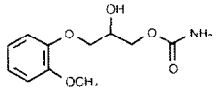
PC4449D
Rev 09/03

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 $C_{11}H_{15}NO_5$ 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

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&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&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 (± 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

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.

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### 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.**

SCHWARZ
PHARMA
Milwaukee WI 53201 USA

Printed in USA

PC4449D Rev 09/03