1. NAME OF THE MEDICINAL PRODUCT

METHOCARBAMOL TABLETS USP 500 MG (DORBAXIN TABLETS)

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each film coated tablet contains:

Methocarbamol USP	500 mg
Excipients	Q.S

Colour: Sunset Yellow FCF &Titanium Dioxide BP

3. PHARMACEUTICAL FORM

Tablet

4. Clinical particulars

4.1 Therapeutic indications

As a short-term adjunct to the symptomatic treatment of acute musculoskeletal disorders associated with painful muscle spasms.

4.2 Posology and method of administration

Route of Administration: Oral

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.

4.3 Contraindications

- Hypersensitivity to Methocarbamol or to any of the other excipients
- Coma or pre-coma states
- Known brain damage or epilepsy
- Myasthenia gravis

4.4 Special warnings and precautions for use

Methocarbamol should be used with caution in patients with renal and hepatic insufficiency.

Since methocarbamol may possess a general CNS depressant effect, patients should be cautioned about combined effects with alcohol and other CNS depressants.

Overdose and Treatments:

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. One adult survived the deliberate ingestion of 22 to 30 grams of methocarbamol

without serious toxicity. Another adult survived a dose of 30 to 50 grams. The principal symptom in both cases was extreme drowsiness. Treatment was symptomatic and recovery was uneventful. However, there have been cases of fatal overdose.
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 haemodialysis in managing overdose is unknown

4.5 Interaction with other medicinal products and other forms of interaction

This product may potentiate the effects of other central nervous system depressants and stimulants including alcohol, barbiturates, anaesthetics and appetite suppressants. The effects of anticholinergics, e.g. atropine and some psychotropic drugs may be potentiated by methocarbamol. Methocarbamol may inhibit the effect of pyridostigmine bromide. Therefore methocarbamol should be used with caution in patients with myasthenia gravis receiving anticholinesterase agents. Little is known about the possibility of interactions with other drugs.

Methocarbamol may cause colour interference in certain screening tests for 5-hydroxyindolacetic acid (5-HIAA) using nitrosoaphthol reagent and in screening tests for urinary vanillymandelic acid (VMA) using the Gitlow method.

4.6 Pregnancy and Lactation

Pregnancy

It is also not known whether methocarbamol can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity.

Safe use of methocarbamol has not been established with regard to possible adverse effects upon foetal development. There have been very rare reports of foetal 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 judgement of the physician the potential benefits outweigh the possible hazards.

Breast-feeding

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.

Fertility
Animal reproductive studies have not been conducted with methocarbamol.

4.7 Effects on ability to drive and use machines

Methocarbamol has moderate influence on the ability to drive and use machines as methocarbamol may cause dizziness or drowsiness, especially if other medications capable of causing drowsiness are also being taken. Patients should be cautioned that if dizziness or drowsiness are experienced these activities have to be avoided

4.8 Undesirable effects

In the table below, undesirable effects are listed by MedDRA system organ class and frequency: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (frequency cannot be estimated from available data).

The most frequent undesirable effect of the drug is headache.

General disorders

Rare: headache, fever, angioneurotic oedema

Gastrointestinal disorders

Very rare: nausea and vomiting

Nervous system disorders

Rare: dizziness

Very rare: blurred vision, drowsiness, tremor, convulsion

Psychiatric disorders

Very rare: restlessness, anxiety, confusion, anorexia

Skin and subcutaneous tissue disorders

Rare: hypersensitive reactions (pruritus, skin rash, urticaria)

Eye disorders

Rare: conjunctivitis with nasal congestion

4.9 Overdose

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. One adult survived the deliberate ingestion of 22 to 30 grams of methocarbamol without serious toxicity. Another adult survived a dose of 30 to 50 grams. The principal symptom in both cases was extreme drowsiness. Treatment was symptomatic and recovery was uneventful. However, there have been cases of fatal overdose.

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 haemodialysis in managing overdose is unknown

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmcotherapeutic group: Muscle relaxants, centrally acting agents; Carbamic acid esters

ATC Code: M03BA03

Methocarbamol is used as a short-term adjunct to the symptomatic treatment of acute musculoskeletal disorders associated with painful muscle spasms.

The mechanism of action of methocarbamol in humans has not been established, but may be due to general central nervous system depression. It has no direct action on the contractile mechanism of striated muscle, the motor end plate or the nerve fibre.

5.2 Pharmacokinetic properties

After oral administration methocarbamol is absorbed rapidly and completely from the gastro-intestinal tract. The substance can be detected in blood already 10 minutes after intake and produces peak plasma concentrations after about 1-3 hours. Its activity derives from the intact molecule and only a small proportion is converted to guaiphenesin.

Plasma half-life in plasma amounts to approximately 2 hours. Methocarbamol and its two main metabolites are bound to glucuronic and to sulfuric acid and are eliminated nearly exclusively via the kidneys. About half of an applied dose is excreted into urine within 4 hours, only a small part of which is eliminated as unchanged methocarbamol. Renally impaired
The clearance of methocarbamol in renally-impaired patients on maintenance haemodialysis was reduced about 40% compared to a normal population, although the mean elimination half-life in these two groups was similar (1.2 versus 1.1 hours, respectively).

Hepatically impaired
In patients with cirrhosis secondary to alcohol abuse, the mean total clearance of methocarbamol was reduced approximately 70% compared to a normal population (11.9 L/hr), and the mean elimination half-life was extended to approximately 3.4 hours. The fraction of methocarbamol bound to plasma proteins was decreased to approximately 40 to 45% compared to 46 to 50% in an age and weight-matched normal population

5.3 Preclinical safety data

The acute toxicity of methocarbamol is comparatively low. In animal testing the following signs of intoxication were observed: ataxia, catalepsy, seizures and coma.

In-vitro and in-vivo examinations as to the genetic toxicology of methocarbamol did not reveal any mutagenic potential.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Hydroxy Propyl Cellulose
Sodium Lauryl Sulfate
Sodium Starch Glycolate
Povidone (K-30)
Purified Water
Croscarmellose sodium
Magnesium Stearate
Colorezy White17F580001
Sunset Yellow FCF
Isopropyl alcohol
Dichloromethane

6.2 Incompatibilities

Not known.

6.3 Shelf life

36 months from the date of manufacturing

6.4 Nature and contents of container<and special equipment for use, administration or implantation>

10 X 1 X 10 Tablets in Alu-PVC Blister Pack

6.5 Special precautions for disposal <and other handling>

No special requirements

7 <APPLICANT/MANUFACTURER>

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