SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Methocarbamol 750mg/5ml oral suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of the oral suspension contains 150mg Methocarbamol.

Excipients with known effect

Each ml of this medicine contains 5.00 mg Sodium benzoate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

White to off-white suspension.

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. Methocarbamol is indicated in adults.

4.2 Posology and method of administration

For oral use.

Posology

Adults

The usual dose is 1500 mg/ml four times daily, but therapeutic response has been achieved with doses as low as 750 mg/ml three times daily.

Elderly

Half the maximum dose or less may be sufficient to produce a therapeutic response.

Paediatric population

The safety and efficacy of Methocarbamol in children and adolescent has not yet been established, therefore no data are available. Methocarbamol should not be used in children.

Hepatically impaired

In patients with chronic hepatic disease the elimination half-life may be prolonged. Therefore, consideration should be given to increasing the dose interval.

Duration of Treatment:

The duration of administration depends on the symptoms induced by increased muscle tone, but should not exceed 30 days.

Method of Administration

For oral use.

Shake well before use.

Take Methocarbamol oral suspension with a glass of water.

4.3 Contraindications

- Hypersensitivity to methocarbamol or to any of the excipients listed in section 6.1.
- Coma or pre-coma states.
- Known brain damage or epilepsy.

- Myasthenia gravis.

4.4 Special warnings and precautions for use

Methocarbamol 750mg/5ml oral suspension 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.

Excipients warnings:

Sodium benzoate (E211) - This medicine contains 5 mg sodium benzoate (E211) in each ml.

This medicinal product contains 12.39 mg sodium per 5ml, equivalent to 0.62% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

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 Fertility, pregnancy and lactation

Fertility

Animal reproductive studies have not been conducted with methocarbamol.

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 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 is administered to a nursing woman.

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

The following 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

The following side effects have also been reported.

Blood and Lymphatic system

Leucopenia.

Cardiovascular system disorders

Flushing, Bradycardia, hypotension and syncope.

General Disorders

Anaphylactic reaction

Gastrointestinal disorders

Dyspepsia, Jaundice (including cholestatic jaundice)

Nervous system disorders

Vertigo, mild muscular in coordination, amnesia, diplopia, nystagmus, insomnia, seizures (including grand mal)

Skin, subcutaneous tissue disorders, and special senses

Metallic taste

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard.

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 Pharmacodynamic properties

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

ATC code: M03BA03.

Methocarbamol 750mg/5ml oral suspension 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

Absorption

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.

Renal impairment

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).

Hepatic impairment

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

Sodium benzoate (E211)

Glycerine

Magnesium Aluminium silicate

Cellulose gum

Citric acid monohydrate

Tri-Sodium citrate dihydrate

Sucralose

Tutti-frutti flavour

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months (unopened)

30 days (opened)

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Methocarbamol 750mg/5ml oral suspension packaged in 180 ml type III Amber glass bottle with PP 28mm white CR closure lined with TE EPE

The package also contains a 10ml oral syringe with markings at 1ml and 0.25 ml intervals, along with an adapter.

6.6 Special precautions for disposal

Wash the syringe with water and let it dry before you use it again.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Rosemont Pharmaceuticals Ltd,

Yorkdale Industrial Park, Braithwaite Street,

Leeds, LS11 9XE, UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 00427/0311

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/03/2026

10 DATE OF REVISION OF THE TEXT

13/03/2026