SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Robaxin-750, 750 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each white, capsule-shaped tablet contains 750 mg methocarbamol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated 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

For oral use.

Posology

Adults: The usual dose is 2 tablets four times daily but therapeutic response has been achieved with doses as low as 1 tablet three times daily.

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

Paediatric population

Not recommended.

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.
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

Robaxin-750 should be used with caution in patients with renal and hepatic insufficiency.

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

Pregnancy
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.
Breastfeeding
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-750 is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

This product may cause drowsiness and patients receiving it should not drive nor operate machinery unless their physical and mental capabilities remain unaffected - especially if other medication capable of causing drowsiness is also being taken.

4.8 Undesirable effects

Adverse reactions reported coincident with the administration of methocarbamol include

*Body as a whole:* Angioneurotic oedema, anaphylactic reaction, fever, headache.

*Cardiovascular system:* Bradycardia, flushing, hypotension, syncope.

*Digestive system:* Dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting.

*Blood and lymphatic system:* Leucopenia.

*Nervous system:* Restlessness, anxiety, tremor, amnesia, confusion, diplopia, dizziness or light-headedness, vertigo, drowsiness, insomnia, mild muscular incoordination, nystagmus, seizures (including grand mal).

*Skin and special senses:* Blurred vision, conjunctivitis with nasal congestion, metallic taste, pruritus, rash, urticaria.

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](http://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.

Robaxin-750 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

Methocarbamol is absorbed from the gastro-intestinal tract 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.

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

Nothing of note to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alginic acid, maize starch, povidone, sodium lauryl sulphate, gelatin, magnesium stearate, talc, sepifilm 002, sepisperse white AP 7001, potable mains water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Amber glass bottles: 60 months
Blister packs: 24 months
HDPE bottles with HDPE child resistant caps: 60 months

6.4 Special precautions for storage

No special storage conditions are necessary.

6.5 Nature and contents of container

Amber glass bottles containing 500, 100 or 6 tablets.
Blister packs containing 56 or 8 tablets.

HDPE bottles with HDPE child resistant caps containing 100 tablets.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Almirall, S.A.
Ronda General Mitre 151
08022 Barcelona
Spain

8 MARKETING AUTHORISATION NUMBER(S)

PL 16973/0015

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th August 2003

10 DATE OF REVISION OF THE TEXT

31/07/2017