Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Methocarbamol 750 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 750mg of methocarbamol.

Excipients with known effect
Lactose monohydrate: each tablet contains 5.5mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.
White to off-white slightly curved oblong film coated tablets with double-sided scoring.
The dimensions of the tablets are: length 19mm, width 8mm and thickness 6.60 ±0.4mm.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

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 750mg film-coated tablets is indicated in adults.

4.2 Posology and method of administration

Dosage:
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
The safety and efficacy of Methocarbamol 750mg film-coated tablets in children and adolescents have not been established. No data are available.

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.

Route of administration
For oral use.

4.3 Contraindications

Hypersensitivity to methocarbamol or any of the other 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 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.

Contains Lactose:
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interactions

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 (5HIAA) using nitrosoaphthol reagent and in screening tests for urinary vanillymandelic acid (VMA) using the Gitlow method.

4.6 Fertility, pregnancy and lactation

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.

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

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 have been reported in the context of treatment with methocarbamol and - as far as information on frequency is stated in the literature - are based on the following groups of 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	(cannot be estimated from the 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

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 by 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 by 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

Tablet core:
Sodium Starch Glycolate Type A
Starch, Pregelatinised
Sodium Lauryl Sulphate
Povidone
Magnesium Stearate

Tablet coating:
Hypromellose
Titanium Dioxide
Lactose Monohydrate
Macrogol
Triacetin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC/PVDC-blisters containing 20, 30, 50 or 100 film-coated tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

HBS Healthcare
Moor Park Avenue
Preston
PR1 6AS
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA2238/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st November 2019

10 DATE OF REVISION OF THE TEXT