SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Methocarbamol 1500 mg film-coated Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 Film-coated tablet contains 1500 mg methocarbamol.

Excipient with known effect:
Each film-coated tablet contains 9.58 to 14.36 mg lactose (as monohydrate).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film coated tablets

The film-coated tablets are White to off-white, oval shaped, biconvex, film-coated tablets plain on both faces with approximate dimension of 23.10 mm in length, 11.10 mm in width.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of painful muscle spasm, especially of the lower back (lumbago).

Methocarbamol 1500 mg film-coated Tablet is indicated in adults.

4.2 Posology and method of administration

Posology

The dose for adults is 1500 mg of methocarbamol 3 times daily. At the beginning of treatment, a dose of 1500 mg of methocarbamol 4 times a day is recommended.

In severe cases, patients may take up to 7500 mg of methocarbamol per day.

Duration of use

Methocarbamol 1500 mg film-coated Tablet should be taken as long as the symptoms of muscle spasm persist, but not longer than 30 days.

Paediatric population

The safety and efficacy of Methocarbamol 1500 mg film-coated Tablet in children and adolescents have not been established.

Method of administration

Methocarbamol 1500 mg film-coated Tablet is for oral use.

The film-coated tablets should be taken with plenty of water.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the other excipients listed in section 6.1.
- Comatose or precomatose states
- Central nervous system (CNS) disorders
- Myasthenia gravis
- Patients with a tendency to epileptic convulsions

4.4 Special warnings and precautions for use

Methocarbamol 1500 mg film-coated Tablet should be used with caution in patients with impaired renal function and/or impaired hepatic function.

Interference with laboratory tests

Methocarbamol may cause color interference in laboratory tests for hydroxyindoleacetic acid (5-HIAA) and vanillin mandelic acid (VMA).

Methocarbamol 1500 mg film-coated Tablet contains lactose.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take this medicinal product.

Methocarbamol 1500 mg film-coated Tablet contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per mg, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicinal products and other forms of interaction

When Methocarbamol is used concomitantly with centrally acting medicinal products such as barbiturates, opioids as well as appetite suppressants, an increased interactive effect may occur.

Consumption of alcohol during treatment with methocarbamol may potentiate the effect.

The effect of anticholinergics, such as atropine, and other psychotropic medicinal products may be potentiated by methocarbamol.

Methocarbamol may attenuate the effect of pyridostigmine bromide. Therefore, methocarbamol must not be taken by patients with myasthenia gravis, especially those treated with pyridostigmine.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is no experience with the use of methocarbamol during pregnancy. No data are available from animal studies with respect to effects on pregnancy, embryonic/fetal development, parturition, and postnatal development (see section 5.3). The potential risk to humans is not known.
Therefore, methocarbamol should not be used during pregnancy.

Breast -feeding
It is not known whether methocarbamol and / or its metabolites pass into breast milk in humans. Methocarbamol and / or its metabolites are excreted into milk in lactating dogs. Therefore, methocarbamol should not be used during lactation.

Fertility
No data are available on the effect of methocarbamol on human fertility.

4.7 Effects on ability to drive and use machines

Methocarbamol 1500 mg film-coated Tablet has a moderate effect on the ability to drive and use machines, as methocarbamol may cause dizziness or sleepiness, especially if other medicinal products are taken at the same time that may also cause sleepiness.

Patients should be advised not to perform these activities if dizziness or drowsiness occurs.

4.8 Undesirable effects

The following categories are used as a basis for the frequency data on side effects (insofar as data on frequency are available from the literature):

Rare	(≥1/10,000 to <1/1,000)
Very rare	(<1/10,000)
Not known	Frequency cannot be estimated on the basis of available data

The following undesirable effects have been reported in association with treatment with methocarbamol:

Organ class system	**Frequency as per MedDRA-convention**		
	Rare	**Very rare**	**Not known**
Infections and infestations	Conjunctivitis		
Immune system disorders		Anaphylactic Reaction	
Metabolism and nutrition disorders		Reduced Appetite	
Psychiatric disorders		Agitation, Anxiety, Confusion	
Nervous system disorders	Headache, Dizziness, Metallic Taste	Syncope, Nystagmus, giddiness, Tremor, Seizure	Somnolence, coordination disorder, Hypoesthesia*, Paresthesia*
Eye disorders		Visual impairment, Double vision	
Cardiac disorders		Bradycardia	
Vascular disorders	Hypotension	Hot flashes	
Respiratory, thoracic and mediastinal disorders	Nasal congestion		
Gastrointestinal disorders		Nausea, Vomiting	Nausea, diarrhea
Skin and subcutaneous tissue disorders	Angioedema, Rash, Pruritus, Urticaria		
General disorders and administration site conditions	Fever		Fatigue

*Localized, temporary sensory disturbance predominantly affecting the head (e.g. face, scalp), the mouth region (e.g. lips, tongue) or the extremities (hands, fingers, feet)

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 at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

After oral ingestion of 22.5 to 50 g of methocarbamol with suicidal intent, two patients experienced sleepiness. Both patients recovered completely within 24 hours. The literature contains 3 instances of deaths in which, in addition to methocarbamol, large amounts of alcohol (2x) or opiates (1x) were taken simultaneously with suicidal intent. Treatment of intoxications consists of symptomatic therapy and monitoring of vital signs. The benefit of hemodialysis in the treatment of overdose is not known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: muscle relaxants, centrally acting agents, carbamic acid esters,
ATC code: M03BA03

Mechanism of action
Methocarbamol is a centrally acting muscle relaxant.

Pharmacodynamic effects
It exerts its muscle relaxant effects via inhibition of polysynaptic reflex conduction in the spinal cord and subcortical centers.

Clinical efficacy and safety
Physiologic skeletal muscle tone and contractility, as well as smooth muscle motility, are not affected by methocarbamol at therapeutic doses, and the motor endplate is not affected.

5.2 Pharmacokinetic properties

Absorption
Methocarbamol is rapidly and completely absorbed after oral administration.

Distribution
The substance is detectable in the blood already 10 minutes after ingestion and after 30 - 60 minutes, the maximum level is reached in the blood. The plasma half-life of methocarbamol is approximately 2 hours.

Biotransformation and elimination
Methocarbamol and its two major metabolites are bound to glucuronic and sulfuric acids and are excreted almost exclusively by the kidneys. Approximately half of the applied dose is excreted in the urine within 4 hours, of which only a small portion is excreted as unchanged methocarbamol.

Renal Impairment
In patients with impaired renal function undergoing long-term hemodialysis treatment, clearance of methocarbamol was reduced by approximately 40% compared with a population with normal renal function, although the mean elimination half-life was similar in these two groups (1.2 and 1.1 hours, respectively).

Hepatic impairment
In patients with alcohol-related cirrhosis, the mean total clearance of methocarbamol was decreased by approximately 70% (11.9 l/h), and the mean elimination half-life was prolonged to approximately 3.4 hours, compared with a population with normal liver function. The fraction of methocarbamol bound to plasma proteins was reduced to approximately 40 to 45%, compared with 46 to 50% in an age- and weight-controlled population with normal liver function.

5.3 Preclinical safety data

The acute toxicity of methocarbamol is comparatively low. Signs of intoxication in animal studies include ataxia, catalepsy, convulsions and coma.

Chronic toxicity and reproductive toxicity studies have not been conducted.

In vitro and in vivo studies on the genotoxicity of methocarbamol revealed no evidence of mutagenic potential.

Long-term studies to clarify a carcinogenic potential were not carried out.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core: maize starch, sodium starch glycolate (type A), povidone k-30, sodium laurilsulfate, stearic acid, magnesium stearate.

Film coating: lactose monohydrate, hypromellose, macrogol 4000, titanium dioxide (E171).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25° C.

6.5 Nature and contents of container

PVC/PE/PVdC-Alu blister pack containing pack size of 8, 10, 96 &100 film-coated tablets.
Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Brown & Burk UK Ltd
Micro House
Bury street
Ruislip
HA4 7TL
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 25298/0375

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/09/2024

10 DATE OF REVISION OF THE TEXT

18/09/2025