SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Methocarbamol 1500 mg film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 1500 mg of methocarbamol.

Excipient with known effect:
Each film-coated tablet contains 11 mg lactose (as monohydrate).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

White to off-white, oval shaped, film coated tablets, debossed with “1500” on one side and plain surface on other side. The tablet dimensions are 23 x 11 mm with a thickness of 9 mm.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of painful muscular tension, especially in the lower back (lumbago).
Methocarbamol is indicated in adults.

4.2 Posology and method of administration

Posology:

Adults

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

In severe cases up to 7500 mg methocarbamol can be taken each day.

The duration of treatment depends on the symptoms of muscle tension but should not exceed 30 days.

Paediatric population

The safety and efficacy of methocarbamol in children and adolescents have not been established.

Elderly patients

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

Patients with hepatic impairment

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

Method of administration

Methocarbamol tablets are for oral use.

The tablets should be swallowed whole and with water.

4.3 Contraindications

- Hypersensitivity to methocarbamol or any of the excipients listed in section 6.1
- Comatose or pre-comatose states
- Disorders of the central nervous system (CNS)
- Myasthenia gravis
- Epilepsy

4.4 Special warnings and precautions for use

Methocarbamol should be used with caution in patients with impaired renal and/or hepatic function.

Interference with laboratory tests

Methocarbamol may cause colour interference in screening tests for 5-hydroxyindolacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Methocarbamol tablets contains lactose and sodium

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

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

4.5 Interaction with other medicinal products and other forms of interaction

The concomitant administration of methocarbamol and centrally acting medicinal products such as barbiturates, opioids and appetite suppressants may potentiate the effect of these products.

Using methocarbamol together with alcohol may potentiate the effect of the medicinal product.

The effects of anticholinergics, such as atropine and other psychotropic medicinal products may be increased by methocarbamol. Consumption of alcohol during methocarbamol treatment may lead to an increased effect.

Methocarbamol may inhibit the effect of pyridostigmine bromide. Therefore, methocarbamol must not be taken by patients with myasthenia gravis especially those who are being treated with pyridostigmine (see section 4.3).

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no experience in the use of methocarbamol during pregnancy. Data from animal studies concerning effects on pregnancy, embryonic/foetal development, parturition and post- natal development are not available (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 human breast milk. Methocarbamol and/or its metabolites are excreted into the milk of lactating dogs. Therefore, methocarbamol should not be used during breast-feeding.

Fertility

No data are available concerning the influence of methocarbamol on human fertility.

4.7 Effects on ability to drive and use machines

Methocarbamol has moderate influence on the ability to drive and use machines as it may cause dizziness or drowsiness - especially if other medicinal products capable of causing drowsiness are also being taken. Patients should be instructed that if dizziness or drowsiness occurs these activities should be avoided.

4.8 Undesirable effects

The following undesirable effects were reported in connection with the use of methocarbamol.

Frequency data for adverse reactions are based on the following categories (where it has been possible to obtain frequency data from the literature):

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 available data	the frequency cannot be estimated from the

System organ class	**Frequency according to MedDRA convention**		
	Rare	**Very rare**	**Not known**
Infections and infestations	Conjunctivitis		
Immune system disorders		Anaphylactic reaction	
Metabolism and nutrition disorder		Decreased appetite	
Psychiatric disorders		Restlessness , anxiety, Confusional state	
Nervous system disorders	Headache, dizziness metallic taste	Syncope, nystagmus, giddiness, tremor, seizures	Somnolence, coordination disturbance
Eye disorders		Visual impairment,	

		diplopia	
Cardiac disorders		Bradycardia	
Vascular disorders	Hypotension	Hot flushes	
Respiratory, thoracic and mediastinal disorders	Nasal congestion		
Gastrointestinal disorders		Nausea, vomiting	
Skin and subcutaneous tissue disorders	Angioedema, rash, pruritus, urticaria		
General disorders and administration site conditions	Pyrexia		

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

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.

After oral intake of 22.5 to 50 g methocarbamol with suicidal intent, two patients experienced drowsiness, but recovered completely within 24 hours.

In the literature, 3 fatal cases have been reported after methocarbamol was ingested with large quantities of alcohol (2 cases) or opiates (1 case) with suicidal intent.

Management of overdose includes gastric lavage, symptomatic therapy and monitoring of vital functions. The usefulness of haemodialysis in managing overdose has not been established.

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 myorelaxant effect by inhibiting the polysynaptic reflexes in the spinal cord and subcortical centres.

Clinical efficacy and safety

The physiological tonus and contractility of the skeletal muscles and the motility of

the smooth muscles are not impaired by methocarbamol at therapeutic doses and there is no effect on the motor endplate.

5.2 Pharmacokinetic properties

Absorption

After oral administration methocarbamol will be absorbed quickly and completely. The active substance is already detectable in the blood 10 minutes after ingestion and the peak blood concentration is reached after 30 - 60 minutes.

Distribution

The plasma half-life of methocarbamol is approximately 2 hours.

Biotransformation and elimination

Methocarbamol and its two main metabolites bind to glucuronic and to sulphuric acid and are almost exclusively excreted via the kidneys. Approximately half of the administered dose is excreted through the urine within 4 hours, with only a small part being in the form of 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. Signs of intoxication in animal studies include ataxia, catalepsy, convulsions and coma.

Studies on chronic toxicity and on reproductive toxicity have not been performed.

In vitro and *in vivo* genetic toxicology studies with methocarbamol did not provide evidence of a mutagenic potential.

Long-term studies to investigate the carcinogenic potential have not been conducted.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Sodium starch Glycolate Type A

Pregelatinised starch (maize)

Sodium Lauryl sulphate

Povidone K29/32

Magnesium stearate

Tablet coating:

Hypromellose

Titanium Dioxide (E171)

Lactose monohydrate

Macrogol 3000

Triacetin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

30 months

6.4 Special precautions for storage

This medicinal product does not require any special storage condition.

6.5 Nature and contents of container

White opaque PVC/PVDC//Al blisters containing 24, 48 or 96 film-coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Consilient Health Limited,
Floor 3, Block 3, Miesian Plaza,
Dublin 2, D02 Y754,
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 24837/0132

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08/04/2022

10 DATE OF REVISION OF THE TEXT

10/01/2024