SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Methocarbamol 750mg 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 the 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.

4.1 Therapeutic indications

As a short-term adjunct to the symptomatic treatment of acute musculoskeletal disorders associated with painful muscle spasms, especially in the area of the back (lumbago).
Methocarbamol 750mg film-coated tablets is indicated in adults.

4.2 Posology and method of administration

Posology

Adults: The usual dose is 2 tablets (1500 mg methocarbamol) three times a day. At the beginning of treatment, a dosage of 2 tablets (1500 mg methocarbamol) four times a day recommended. In severe cases, patients may take 2 tablets (1500 mg methocarbamol) five times (7500 mg methocarbamol) per day.
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.
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.

The coated tablets are swallowed with a large amount of water.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Coma or pre-coma states.
Central nervous system (CNS) disease.
Known brain damage or epilepsy.
Myasthenia gravis.

4.4 Special warnings and precautions for use

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

Methocarbamol may potentiate the effects of other centrally acting medicinal products such as barbiturates, opioids and appetite suppressants.
Drinking alcohol while taking methocarbamol may increase the effect.

The effects of anticholinergics, e.g. atropine and other psychotropic drugs may be increased by methocarbamol.

Methocarbamol may inhibit the effect of pyridostigmine bromide. Therefore, methocarbamol should not be used in patients with myasthenia gravis, especially those treated with pyridostigmine.

Interference with laboratory tests:
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

There is no experience with the use of methocarbamol during pregnancy. There are no data from animal studies regarding effects on pregnancy, embryonal/foetal development, parturition and postnatal development (see section 5.3). The potential risk to humans is unknown. Therefore, methocarbamol should not be used during the pregnancy.

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.
Therefore, methocarbamol should not be used during breast-feeding.

Fertility

There are no data available on the effect 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 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	(≥1/1000 to <1/100)
Rare	(≥1/10000 to <1/1000)
Very rare	(<1/10000)
Not known	(cannot be estimated from the available data)

	Frequency according to the MedDRA convention		
System organ class	Rare	Very rare	Not known
Infections and infestations	Conjunctivitis		
Immune system disorders		Anaphylactic reaction	
Metabolism and nutrition disorders		Decreased appetite	
Psychiatric disorders		Unrest Anxiety Confusion	
Nervous system disorders	Headache Vertigo Metallic taste	Syncope Nystagmus Drowsiness Tremor Seizure	Drowsiness Coordination disorder Hypoesthesia* Paraesthesia*
Eye disorders		Visual impairment Double vision	
Cardiac disorders		Bradycardia	
Vascular disorders	Hypotension	Hot flash	
Respiratory, thoracic and mediastinal disorders	Swelling of the nasal mucosa		
Gastrointestinal disorders		Nausea Vomiting	Nausea Diarrhoea
Skin and subcutaneous tissue disorders	Angioedema Rash Pruritus Urticaria		
General disorders and administration site conditions	Fever		Fatigue

- Localized, transient sensory disturbances primarily affecting the head (e.g. face, scalp), mouth area (e.g. lips, tongue) or extremities (hand, 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/yellocard or by searching 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. Two patients developed somnolence after oral ingestion of 22.5 to 50 g of methocarbamol with suicidal intent. Both patients fully recovered within 24 hours. In the literature, there are 3 deaths in which, in addition to methocarbamol, a large amount of alcohol (2x) or opiates (1x) was administered at the same time with suicidal intent.

Treatment of intoxication consists of symptomatic therapy and monitoring of vital functions. The benefits of haemodialysis in the treatment of overdose is unknown.

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 effect: It exerts muscle-relaxing effect by inhibiting polysynaptic reflex conduction in the spinal cord and subcortical centres.

Clinical efficacy and safety : Physiological tone and contractility of skeleton muscle and smooth muscle motility are not affected by methocarbamol at therapeutic doses and the motor endplate is not affected.

5.2 Pharmacokinetic properties

Absorption:

After oral administration methocarbamol is absorbed rapidly and completely from the gastro-intestinal tract.

Distribution:

The substance can be detected in blood as early as 10 minutes after intake and the maximum level of active substance in the blood is reached after 30-60 minutes .Plasma half-life in plasma amounts to approximately 2 hours.

Biotransformation and elimination:

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 administered dose is excreted into urine within 4 hours, only a small part of which is eliminated as unchanged methocarbamol.

Renally impairment in patients:

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, convulsions and coma.
Chronic toxicity and reproduction toxicity studies have not been performed.

In-vitro and in-vivo examinations as to the genetic toxicology of methocarbamol did not reveal any mutagenic potential.

Long-term studies to clarify the carcinogenic potential have not been performed.

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

36 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

No special requirements.

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

7 MARKETING AUTHORISATION HOLDER

Activase Pharmaceuticals Ltd.

11 Boumpoulinas,

1060,

Nicosia, Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 28444/0236

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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