SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Methocarbamol neuraxpharm 750 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 750 mg methocarbamol.

Excipients with known effect:

Each film-coated tablet contains 22.37 mg lactose (as monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

White, oblong, biconvex film-coated tablets with a score line on one side, size: 19.1 mm x 8.1 mm.

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

Symptomatic treatment of painful muscle tension, in particular low back pain (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 treatment a dose of 1500 mg methocarbamol 4 times a day is recommended.

In severe cases up to7500 mg methocarbamol per day can be taken.

The duration of treatment depends on the symptoms induced by 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 is for oral use.

The film-coated tablets should be taken with sufficient water.

4.3 Contraindications

- Hypersensitivity to the active substance or to 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.

Patients should be advised that the intake of alcohol during the treatment with methocarbamol or a combination with other centrally acting agents can lead to an increase in effects.

Methocarbamol tablets contain lactose

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

Methocarbamol tablets contain sodium

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

Interference with laboratory tests

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

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 mutually potentiate the effects of the medicinal products.

Methocarbamol can potentiate the effect of anticholinergic medicinal products such as atropine and some psychotropic medicinal products.

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

Methocarbamol may inhibit the effect of pyridostigmine bromide. Therefore methocarbamol must not be administered to patients with myasthenia gravis receiving pyridostigmine.

4.6 Fertility, Pregnancy and lactation

Pregnancy

There is no experience in the use of methocarbamol during pregnancy. Animal studies have not established safe use of methocarbamol with regard to effects upon pregnancy, embryonic/foetal development, parturition and postnatal development (see section 5.3). The potential risk for 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 milk. Methocarbamol and/or its metabolites are excreted into the milk of lactating dogs. Therefore methocarbamol should not be used by breast-feeding women.

Fertility

Animal reproductive studies have not been conducted with methocarbamol.

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. Possible undesirable effects of methocarbamol may affect the patient's ability to drive and use machines.

4.8 Undesirable effects

The following undesirable effects were reported in connection with the use of methocarbamol. The frequency of possible undesirable effects - if relevant data are given in literature - is defined using the following conventions:

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 (frequency cannot be estimated from the available data)

Infections and infestations	
Rare	Conjunctivitis
Immune system disorders	
Very rare	Anaphylactic reaction
Metabolic and nutrition disorders	
Very rare	Anorexia
Psychiatric disorders	
Very rare	Unrest, anxiety, confusion
Nervous system disorders	
Rare	Headache, vertigo, metallic taste
Very rare	Syncope, nystagmus, dizziness, tremor, convulsion
Not known	Drowsiness
Eye disorders	

Very rare	Impaired vision
Cardiac disorders	
Very rare	Bradycardia
Vascular disorders	
Rare	Hypotension
Very rare	Hot flushes
Respiratory, thoracic and mediastinal disorders	
Rare	Nasal congestion
Gastrointestinal disorders	
Very rare	Nausea, vomiting
Skin and subcutaneous tissue disorders	
Rare	Angioneurotic oedema, itching, skin rash, urticaria
General disorders and administration site conditions	
Rare	Fever

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

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 showed drowsiness, but recovered completely within 24 hours.

In literature 3 fatal cases are mentioned when patients in addition to methocarbamol consumed large quantities of alcohol (2 cases) or took 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

Methocarbamol is a centrally acting muscle relaxant. Its muscle relaxing action is the result of the inhibition of polysynaptic reflexes in the spinal marrow and subcortical centres. Methocarbamol, at the therapeutic dose, does not affect the physiological tonus and contractility of the skeletal muscles as well as the motility of non-striated muscles, and has no action on the motor end plate.

5.2 Pharmacokinetic properties

After oral administration methocarbamol is absorbed quickly and completely. The active substance can be detected in blood already 10 minutes after intake and produces peak blood concentrations after 30 -60 minutes.

Plasma half-life of methocarbamol is ca. 2 hours. Methocarbamol and its two metabolites are bound to glucuronic and sulfuric acid and are eliminated nearly exclusively via the kidneys. About half the dose administered is excreted into urine within 4 hours, only a small portion of which is eliminated as unchanged methocarbamol.

<u>Renally impaired</u>

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 are ataxia, catalepsy, convulsions and coma.

Studies on chronic toxicity have not been performed.

Studies to determine a potential toxicity on reproduction have not been carried out.

In vitro and *in vivo* studies on genetic toxicity of methocarbamol did not reveal evidence of a mutagenic potential.

Long-term studies for evaluation of a carcinogenic potential have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Lactose monohydrate
Croscarmellose sodium
Sodium lauryl sulfate
Povidone
Silica, colloidal anhydrous
Magnesium stearate

Film-coating:
Polyvinyl alcohol
Titanium dioxide (E171)
Talc
Macrogol 3350

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

PVC/ACLAR//Al blisters
This medicinal product does not require any special storage conditions.

Polyvinylchloride (PVC)/ aluminium blister
Do not store above 30ºC.

6.5 Nature and contents of container

PVC/ACLAR//Al blisters and Polyvinylchloride (PVC)/ aluminium blister

Pack sizes: 20, 50 or 100 film-coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Neuraxpharm UK Limited
First Floor, Building 1410,
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United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 49718/0022

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/02/2025

10 DATE OF REVISION OF THE TEXT

28/04/2026