**SUMMARY OF PRODUCT CHARACTERISTICS**

# NAME OF THE MEDICINAL PRODUCT

# <TRADE NAME> <STRENGTH> film-coated Tablets

# <REGARDING THE APPROVAL>

# QUALITATIVE AND QUANTITATIVE COMPOSITION

# Each film-coated tablet contains <STRENGTH> <GENERIC NAME>

# Excipient with known effect:

# <REGARDING THE APPROVAL>

# For the full list of excipients, see section 6.1

# PHARMACEUTICAL FORM

# Film-coated tablet

# <REGARDING THE APPROVAL>

# CLINICAL PARTICULARS

# Therapeutic indications

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

<GENERIC NAME> is indicated in adults.

* 1. **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.

## Contraindications

## Hypersensitivity to <GENERIC NAME> 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

## Special warnings and precautions for use

## <GENERIC NAME> should be used with caution in patients with impaired renal and/or hepatic function.

## Interference with laboratory tests

<GENERIC NAME> may cause colour interference in screening tests for 5hydroxyindolacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

<GENERIC NAME> 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’.

## Interaction with other medicinal products and other forms of interaction

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

Using <GENERIC NAME> 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 <GENERIC NAME>. Consumption of alcohol during <GENERIC NAME> treatment may lead to an increased effect.

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

## Fertility, pregnancy and lactation

## Pregnancy

There is no experience in the use of <GENERIC NAME> 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, <GENERIC NAME> should not be used during pregnancy.

Breast-feeding

It is not known whether <GENERIC NAME> and/or its metabolites pass into human breast milk. <GENERIC NAME> and/or its metabolites are excreted into the milk of lactating dogs. Therefore, <GENERIC NAME> should not be used during breastfeeding.

Fertility

No data are available concerning the influence of <GENERIC NAME> on human fertility.

## Effects on ability to drive and use machines

## <GENERIC NAME> 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.

## Undesirable effects

The following undesirable effects were reported in connection with the use of <GENERIC NAME>.

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 Health Product Vigilance Center; HPVC

## Overdose

## Limited information is available on the acute toxicity of <GENERIC NAME>. Overdose of <GENERIC NAME> 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 <GENERIC NAME> with suicidal intent, two patients experienced drowsiness, but recovered completely within 24 hours.

In the literature, 3 fatal cases have been reported after <GENERIC NAME> 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.

## PHARMACOLOGICAL PROPERTIES

## Pharmacodynamic properties

## Pharmacotherapeutic group: Muscle relaxants, centrally acting agents; Carbamic acid esters.

## ATC Code: M03BA03

Mechanism of action

<GENERIC NAME> 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 <GENERIC NAME> at therapeutic doses and there is no effect on the motor endplate.

### Pharmacokinetic properties

### Absorption

After oral administration <GENERIC NAME> 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 <GENERIC NAME> is approximately 2 hours.

Biotransformation and elimination

<GENERIC NAME> 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 <GENERIC NAME>.

Renally impaired

The clearance of <GENERIC NAME> 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 <GENERIC NAME> 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 <GENERIC NAME> bound to plasma proteins was decreased to approximately 40 to 45% compared to 46 to 50% in an age and weight-matched normal population.

* 1. **Preclinical safety data**

The acute toxicity of <GENERIC NAME> 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 <GENERIC NAME> did not provide evidence of a mutagenic potential.

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

## PHARMACEUTICAL PARTICULARS

## List of excipients

## <REGARDING THE APPROVAL>

* 1. **Incompatibilities**

<REGARDING THE APPROVAL>

* 1. **Shelf life**

<REGARDING THE APPROVAL>

* 1. **Special precautions for storage**

<REGARDING THE APPROVAL>

* 1. **Nature and contents of container**

<REGARDING THE APPROVAL>

* 1. **Special precautions for disposal**

<REGARDING THE APPROVAL>

1. **MARKETING AUTHORISATION HOLDER**

<REGARDING THE APPROVAL>

1. **MARKETING AUTHORISATION NUMBER(S)**

<REGARDING THE APPROVAL>

## DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

## <REGARDING THE APPROVAL>

## DATE OF REVISION OF THE TEXT[[1]](#footnote-1)

## <REGARDING THE APPROVAL>

1. Ref: Methocarbamol , MHRA, 08/04/2022 [↑](#footnote-ref-1)