1. NAME OF THE MEDICINAL PRODUCT

Methocarbamol Aristo 750 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 750 mg methocarbamol.
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet
White, oblong tablets (19 mm x 8 mm)

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of painful muscle tone, especially in the low back region (lumbago).

Methocarbamol is used in adults.

4.2 Posology and method of administration

Posology
The dosage for adults is 1500 mg methocarbamol three times a day.
For the start of treatment, intake of 1500 mg methocarbamol four times a day is recommended. In the case of severe complaints, patients may take up to 7500 mg methocarbamol per day.

Duration of administration
Methocarbamol should be taken for as long as the symptoms induced by increased muscle tone persist, but should not exceed 30 days.

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.

Paediatric population
The safety and efficacy of Methocarbamol Aristo in children and adolescents have not been established.

Method of administration
Methocarbamol Aristo is for oral use.
The tablets should be taken with a sufficient amount of 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,
- diseases of the central nervous system,
- Myasthenia gravis,
- Patients with a predisposition to epileptic seizures

4.4 Special warnings and precautions for use

Methocarbamol should be used with special care in patients with impaired renal function and/or impaired liver function.

Interference with laboratory tests
The urine of some patients receiving methocarbamol has been reported to turn brown, black, blue or green when stored. Methocarbamol may cause colour interference in certain screening tests for hydroxyindolacetic acid (5-HIAA) and for vanillylmandelic acid (VMA).

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

4.5 Interactions with other medicinal products and other forms of interaction

In the case of the concomitant use of methocarbamol and centrally acting medicinal products such as barbiturates, opioids or appetite suppressants pharmacological effects may mutually be enhanced.

If alcohol is taken during treatment with methocarbamol, an increase in effect may occur.

The effects of anticholinergics, e.g. atropine and some other psychotropic drugs may be potentiated by methocarbamol. Methocarbamol may decrease the effect of pyridostigmine bromide. Therefore, methocarbamol must not be taken by patients with myasthenia gravis, particularly those being treated with pyridostigmine.

4.6 Fertility, Pregnancy and lactation

Pregnancy
There is no experience concerning the use of methocarbamol during pregnancy. Animal studies have not established the safe use of methocarbamol with regard to effects on pregnancy, embryonic/fetal 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
No data are available about the influence of Methocarbamol on the human fertility.

4.7 Effects on the ability to drive and use machines

Methocarbamol may have an influence on the ability to drive and use machines since methocarbamol can cause dizziness and sleepiness, especially in concomitant use with other medications which also can cause sleepiness.
Patients should be advised not to carry out these activities in case dizziness or sleepiness occur.

4.8 Undesirable effects

The following groups have been used for frequency of undesirable effects:

very common	(≥ 1/10)
common	(≥ 1/100, < 1/10)
uncommon	(≥ 1/1000, < 1/100)
rare	(≥ 1/10 000, < 1/1000)
very rare	(< 1/10 000)
not known	(frequency cannot be estimated from the available data)

Immune system disorders
Very rare: anaphylactic reaction

Metabolism and nutrition disorders
Very rare: decreased appetite

Psychiatric disorders
Very rare: restlessness, anxiety, confusion

Nervous system disorders
Rare: headache, dizziness, metallic taste
Very rare: syncope, nystagmus, drowsiness, tremor, convulsions
Not known: sleepiness, loss of coordination, hypoesthesia*, paraesthesia*

Eye disorders
Rare: conjunctivitis
Very rare: visual impairment, double vision

Cardiac disorders
Very rare: bradycardia

Vascular disorders
Rare: hypotonia
Very rare: hot flash

Respiratory, thoracic and mediastinal disorders
Rare: swelling of the nasal mucosa

Gastrointestinal disorders
Very rare: feeling sick, vomiting
Not known: nausea, diarrhoea

Skin and subcutaneous tissue disorders
Rare: angioedema, skin rash, pruritus, urticaria

General disorders and administration site conditions
Rare: fever
Not known: fatigue

*Localised,temporary sensory disorders predominantly affecting the head (e.g. face, scalp), the mouth region (e.g. lips and tongue) or the limbs (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

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.

Following oral use of methocarbamol in doses of 22.5 g to 50 g by patients who intended to commit suicide, sleepiness was observed in two patients. Both patients recovered completely within 24 hours. There are 3 reported death cases in the literature, which involved the concomitant use of large quantities of alcohol (2x) and opiates (1x) alongside methocarbamol with suicidal intent.

Treatment of intoxication comprises symptomatic therapy and monitoring of vital functions.
The benefit of hemodialysis in the treatment of a methocarbamol 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
Its myotonolytic effect is based on an inhibition of polysynaptic reflex conduction within the spinal cord and subcortical structures.

Clinical efficacy and safety
The physiological tone and contractility of skeletal muscle as well as the motility of smooth muscle are not affected by methocarbamol in therapeutic doses which also has no impact on the motor end plate.

5.2 Pharmacokinetic properties

Resorption
After oral administration methocarbamol is absorbed rapidly and completely.

Distribution
The substance can be detected in blood already 10 minutes after intake. Peak plasma levels are achieved 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 applied dose is excreted into urine within 4 hours, only a small part of which is eliminated as unchanged methocarbamol.

Renal impairment
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 alcohol-related cirrhosis, the mean total clearance of methocarbamol was reduced by approximately 70% compared to the population with normal liver function (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 and reproductive toxicity have not been performed.

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

Sodium starch glycolate (type A)
Magnesium stearate
Povidone K25

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC/PVDC/aluminium blister
Pack sizes: 20, 50 and 100 tablets
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Aristo Pharma GmbH
Wallenroder Str. 8-10
13435 Berlin
Germany

8 MARKETING AUTHORISATION NUMBER(S)

PL 40546/0160

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04/10/2022

10 DATE OF REVISION OF THE TEXT

18/03/2025