Package leaflet: Information for the patient

Methocarbamol 750 mg Tablets
Methocarbamol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Methocarbamol is and what it is used for
2. What you need to know before you take Methocarbamol
3. How to take Methocarbamol
4. Possible side effects
5. How to store Methocarbamol
6. Contents of the pack and other information

1. What Methocarbamol is and what it is used for

Methocarbamol tablets contain the active substance methocarbamol. Methocarbamol belongs to a group of medications described as muscle relaxants.
Methocarbamol is used for the symptomatic treatment of painful muscle spasms, especially in the lower back (lumbago).

Methocarbamol is used in adults.

2. What you need to know before you take Methocarbamol

Do not take Methocarbamol
- if you are allergic to methocarbamol or any of the other ingredients of this medicine (listed in section 6).
- if you have ever suffered from a coma or reduced consciousness.
- if you suffer from any disorders of the central nervous system.
- if you suffer from abnormal muscle weakness (known as 'Myasthenia gravis')
- if you suffer from epileptic seizures

Warnings and precautions
Talk to your doctor or pharmacist before taking Methocarbamol
- if you suffer from kidney and/or liver problems.

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

Use in children and adolescents
This medicine is not recommended for use in children aged to 12 years and adolescents due to a lack of data.

Other medicines and Methocarbamol
Tell your doctor or pharmacist if you are taking, have recently taken/used or might take/use any other medicines including medicines obtained without prescription.

Taking Methocarbamol at the same time as certain medicines such as barbiturates, opioids or appetite suppressants may increase the effect of these medicines.

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

Methocarbamol may decrease the effect of pyridostigmine bromide. Therefore methocarbamol must not be used in patients with abnormal muscle weakness (myasthenia gravis), especially those being treated with pyridostigmine.

Methocarbamol with alcohol
Alcohol may increase the effects of methocarbamol.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
If you are pregnant you should not take this medicine since the safe use of Methocarbamol has not been established.

Breast-feeding
It is not known whether methocarbamol and/or its metabolites are passed into human milk. Therefore, you should not use this medicine if you are breast-feeding.

Fertility
No data are available about the effects of Methocarbamol on human fertility.

Driving and using machines
Methocarbamol may affect your ability to drive and use machines. Before driving or using machines, you should consider your general health and the possible side effects of Methocarbamol (see section 4) and you should not drive or use machines if you experience any side effects such as dizziness or sleepiness.

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

3. How to take Methocarbamol

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose

Adults
Unless otherwise prescribed, the recommended dosage is 2 tablets taken three times a day. At the start of treatment, it is recommended to take 2 tablets four times a day.
In severe cases, up to 7500 mg Methocarbamol (10 tablets) daily may be taken.

Elderly patients
Elderly patients may only need half the usual dose to give the same relief from the pain and muscle spasms.

Liver problems
You may need a longer interval between taking the tablets if you have liver disease.
You should always follow your doctor's instructions carefully.

How to take the tablets
Methocarbamol is for oral use. The tablets should be taken with a glass of water (approx. 200 ml).

How long should you take the tablets
The duration of treatment depends on your symptoms but should not exceed 30 days.

If you take more Methocarbamol than you should
Please contact your doctor immediately. He-she will decide what to do.

If you forget to take Methocarbamol
Do not take a double dose to make up for a forgotten dose. Please take the next dose at the usual time.

If you stop taking Methocarbamol
Please tell your doctor if you wish to stop your treatment with Methocarbamol. There are unlikely to be any unwanted effects on stopping your treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare side effects (may affect up to 1 in 1,000 people)
- conjunctivitis
- headache
- dizziness
- metallic taste
- decrease in blood pressure
- swelling of the nasal mucosa
- angioedema (a serious allergic reaction which causes swelling of the face or throat)
- rash
- itching
- urticaria (itchy skin)
- fever.

Very rare side effects (may affect up to 1 in 10,000 people)
- anaphylactic reactions (allergic hypersensitivity reactions)
- loss of appetite
- restlessness
- anxiety
- confusion
- fainting
- nystagmus (rapid, uncontrollable eye movements)
- drowsiness
- tremor
- convulsions
- blurred vision
- double vision
- slowed heartbeat
- hot flush
- feeling sick
- vomiting.

Side effects with unknown frequency (frequency cannot be estimated from the available data)
- sleepiness
- loss of coordination
- local temporary sensory disorders (predominantly in the area of the face, scalp, lips, hands, fingers or feet),
- nausea
- diarrhoea
- fatigue.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Methocarbamol

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Methocarbamol tablets contain
The active substance is methocarbamol. Each tablet contains 750 mg methocarbamol.
The other ingredients are sodium starch glycolate (type A), magnesium stearate and povidone K25.

What Methocarbamol looks like and contents of the pack
Methocarbamol 750 mg tablets are white, slightly convex, oblong tablets.

Methocarbamol is available in packs containing 20, 50 and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Aristo Pharma GmbH
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13435 Berlin
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This leaflet was last revised in 11/2024.

ARTWORK DETAILS	
Customer	Aristo Pharma GmbH
Product Name	Methocarbamol 750mg tablets PIL UK
Market	United Kingdom (UK)
Language/s	English
Laetus code.:	n/a
Item Code	50014213/1
Manufacturer Code	GI917000-10/UK/1124
Our Ref	Methocarbamol_750mg_tablets_PIL_UK_ver11 — (** **to follow final proof**)
Issue	**11**
Date	**19 March 2025**

SPECIFICATION DETAILS	
Origination	13 December 2021 — (as Issue 01)
Dimensions	165 x 580 mm
Border	12 mm
Pharmacode No.	661 (Placement to be verified)
Font details	**Main title:** Frutiger LT Std - 75 Black - 18pt **Sub-titles:** Frutiger LT Std - 75 Black — 12 pt **Body copy:** Frutiger LT Std - 55 Roman — 10 pt
Colours	Black - K