Package Leaflet: Information for the patient

Methocarbamol 1500 mg film-coated 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 tablets are and what they are used for

The name of your medicine is Methocarbamol 1500 mg film-coated tablets, referred to as Methocarbamol tablets throughout this leaflet.

Methocarbamol tablets contain the active substance methocarbamol. Methocarbamol belongs to the group of medicinal products known as muscle relaxants.

Methocarbamol is used for the symptomatic treatment of painful muscular tension, especially in the lower back (lumbago).

Methocarbamol tablets are used in adults.

2. What you need to know before you take Methocarbamol tablets

Do not take Methocarbamol tablets

- if you are allergic to methocarbamol or any of the other ingredients of this medicine (listed in section 6)
- in the event of comatose or pre-comatose states
- if you suffer from nervous system (CNS) disorders
- if you suffer from pathological muscle weakness (myasthenia gravis)
- if you suffer from epilepsy

Warnings and precautions
Talk to your doctor or pharmacist before taking methocarbamol:
- if you suffer from impaired kidney function and/or impaired liver function
- if you are having any medical investigations or tests as methocarbamol could interfere with the results. Tell your doctor that you are taking methocarbamol before you have the test

Children and adolescents
This medicinal product is not intended for use in children and adolescents as safety and efficacy in these patient groups have not been established.

Other medicines and Methocarbamol tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The concomitant administration of methocarbamol and centrally acting medicinal products such as barbiturates, opiate derivates and appetite suppressants may potentiate the effect of these medicines.

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

Methocarbamol may inhibit the effect of pyridostigmine bromide. Therefore methocarbamol must not be taken by patients with pathological muscle weakness (myasthenia gravis), who are being treated with pyridostigmine.

Methocarbamol tablets with alcohol
Consumption of alcohol during methocarbamol treatment may potentiate the effect of the medicine. Do not drink alcohol while you are taking Methocarbamol tablets.

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
There is no experience available concerning the use of methocarbamol during pregnancy. The potential risk to humans is not known. You should not take methocarbamol during pregnancy.

Breast-feeding
It is not known whether methocarbamol and/or its metabolites pass into human milk. As a precautionary measure, you should not take Methocarbamol tablets if you are breast-feeding.

Fertility
No data are available concerning the influence of methocarbamol on human fertility.

Driving and using machines

Methocarbamol may affect your ability to drive and use machines. It may make you feel dizzy and drowsy.

Before you consider driving a vehicle or operating machinery, you should consider your state of health and the possible side effects of methocarbamol.

Therefore, you should not perform these activities until you have sufficient experience to know that you have no such side effects.

Information about some of the ingredients of this medicine

Methocarbamol tablets contain **lactose.** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take Methocarbamol tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Unless otherwise prescribed by the doctor, the recommended dose for adults is 1500 mg 3 times a day (corresponding to 1 tablet 3 times daily).

At the beginning of treatment, the recommended dose is 1500 mg 4 times a day (corresponding to 1 tablet 4 times a day).

In very serious cases, a dose up to 7500 mg methocarbamol can be taken each day.

Elderly

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

Liver impairment

You may need a longer interval between taking the tablets if you have liver disease.

You should always follow your doctor's instructions carefully.

Route of administration

Methocarbamol tablets are for oral use.

Take the tablets with sufficient water.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

The duration of treatment depends on the symptoms caused by muscle tension, but should not exceed 30 days.

If you take more Methocarbamol tablets than you should

If you have taken too many Methocarbamol tablets, call your doctor straight away. The doctor will decide about the necessary actions.

If you forget to take Methocarbamol tablets

If you forget to take a dose, take the next dose when it is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Methocarbamol tablets

Inform your doctor if you intend to discontinue treatment with Methocarbamol tablets. Discontinuation is not expected to lead to any special effect.

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 (may affect up to 1 in 1,000 people):

Conjunctivitis, headache, dizziness, metallic taste, decreased blood pressure, nasal congestion, angioedema (acute-onset swelling of parts of the tissue and skin), rash, itching, nettle rash (urticaria), fever

Very rare (may affect up to 1 in 10,000 people):

Anaphylactic reactions (allergic hypersensitivity reactions), loss of appetite, restlessness, anxiety, confusion, fainting, involuntary eye movement, giddiness, trembling, seizures, impaired vision, slow heart beat, hot flushes, retching (nausea) and vomiting

Not known (frequency cannot be estimated from the available data):

Drowsiness, disturbance of coordination

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 Website: 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 tablets

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.

For PVC/aluminium blister packs

Do not store above 30ºC.

For ACLAR/aluminium blister packs:

No special storage conditions are required for this medicinal product.

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

6. Contents of the pack and other information

What Methocarbamol tablets contain

- The active substance is methocarbamol.
  Each film-coated tablet contains 1500 mg methocarbamol.
- The other ingredients are:
  Tablet core: lactose monohydrate, croscarmellose sodium, sodium laurilsulfate, povidone, anhydrous colloidal silica, magnesium stearate.
  Film-coating: poly(vinylalcohol), titanium dioxide (E171), talc, macrogol 3350

What Methocarbamol tablets look like and contents of the pack

Methocarbamol 1500 mg film-coated tablets are white, oblong, biconvex, film-coated tablets, 23 mm x 10 mm, with a score line on one side.
The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Methocarbamol 1500 mg film-coated tablets are available in packs containing 100 or 100 (2 packs of 50) film-coated tablets.
Not all pack sizes may be marketed.

The tablets in this pack are enclosed in PVC/aluminium blister strips.
The tablets in this pack are enclosed in ACLAR/aluminium blister strips.

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