

## **Package leaflet: Information for the patient**

### **Methocarbamol 750 mg film-coated tablets**

**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
2. What you need to know before you take Methocarbamol tablets
3. How to take Methocarbamol tablets
4. Possible side effects
5. How to store Methocarbamol tablets
6. Contents of the pack and other information

#### **1. What Methocarbamol tablets are and what they are used for**

The name of your medicine is Methocarbamol 750 mg film-coated tablets, referred to as Methocarbamol tablets throughout this leaflet.

Methocarbamol tablets contain methocarbamol, an active substance used to treat muscle tension.

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 disorders of the central nervous system
- if you suffer from pathological muscle weakness (myasthenia gravis)
- if you tend to have epilepsy

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Methocarbamol tablets:

- if you suffer from impaired kidney and / or 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 medicine 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/ using, have recently taken/ used or might take/ use any other medicines.

The concomitant administration of methocarbamol and centrally acting medicines such as barbiturates, opiate derivatives and appetite suppressants may potentiate the effects of the 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 administered to patients with pathological muscle weakness (myasthenia gravis) receiving pyridostigmine.

### **Methocarbamol tablets with alcohol**

Using methocarbamol together with alcohol may potentiate the effect of the medicine. Do not drink alcohol while you are taking methocarbamol.

### **Pregnancy and breast-feeding**

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 Methocarbamol tablets, since the safe use of methocarbamol during pregnancy has not been established.

#### Breast-feeding

It is not known whether methocarbamol and/or its metabolites are excreted into human milk. Therefore, you should not take Methocarbamol tablets if you are breast-feeding.

### **Driving and using machines**

Methocarbamol may affect your ability to drive and use machines. Methocarbamol may make you feel sleepy and may affect your ability to drive, operate machinery and carry out other hazardous activities.

Before you consider driving a vehicle or using machines, you should take account of your state of health and the possible side effects of methocarbamol. You should therefore refrain from these activities until you have sufficient experience to know that you will not suffer any 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 medicine.

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 or pharmacist if you are not sure.

#### *Adults*

Unless otherwise prescribed by your doctor, the usual dose for adults is 1500 mg methocarbamol (2 film-coated tablets) 3 times a day. At the beginning of the treatment a dose of 1500 mg methocarbamol (2 film-coated tablets) 4 times a day is recommended.

In severe cases up to 7500 mg methocarbamol (10 film-coated tablets) per day can be taken.

#### *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.

### **Method 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 difficulties in swallowing it whole and not to divide the tablet into equal doses.

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

### **If you take more Methocarbamol tablets than you should**

Inform your doctor who will decide what measures to take.

**If you forget to take Methocarbamol tablets**

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

**If you stop taking Methocarbamol tablets**

Please inform your doctor if you intend to discontinue the treatment with Methocarbamol. Special effects of discontinuation of the medicine are not to be expected.

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)**

- Reddening of the eyes (conjunctivitis) with nasal congestion
- Headache, vertigo, metallic taste
- Low blood pressure
- Angioneurotic oedema
- Itching, skin rash, urticaria, fever

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

- Shock reaction
- Loss of appetite
- Unrest, anxiety, confusion
- Fainting, involuntary eye movement, dizziness, tremor, convulsion
- Impaired vision
- Slow heartbeat
- Hot flushes
- Nausea, vomiting

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

- Drowsiness

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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](http://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.

PVC/ACLAR//Al blisters

This medicine does not require any special storage conditions.

Polyvinylchloride (PVC)/ aluminium blister

Do not store above 30°C.

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 750 mg tablets contain**

The active substance is methocarbamol.

Each film-coated tablet contains 750 mg methocarbamol.

The other ingredients are:

*Tablet core:* lactose monohydrate, croscarmellose sodium, sodium lauryl sulfate, povidone, colloidal anhydrous silica, magnesium stearate.

*Film-coating:* polyvinyl alcohol, titanium dioxide (E 171), talc, macrogol 3350.

### **What Methocarbamol 750 mg film-coated tablets look like and contents of the pack**

White, oblong, biconvex, film-coated tablets with score line on one side, size: approx. 19 x 8 mm.

The score line is only there to help you break the tablet if you have difficulties in swallowing it whole and not to divide the tablet into equal doses.

Methocarbamol 750 mg film-coated tablets are available in packs of 20, 50 and 100 film-coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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