

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Methocarbamol 750mg Film-Coated Tablets**

#### **READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START USING 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. 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 belongs to a group of medicines called ‘muscle relaxants’. They are used for the symptomatic treatment of painful muscle spasms in adults.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE METHOCARBAMOL**

##### **Do not take Methocarbamol if you:**

- are allergic (hypersensitive) to methocarbamol or have had any problems in the past with methocarbamol
- are allergic to any of the other ingredients of this medicine (listed in Section 6)
- have ever suffered any brain damage or coma
- suffer from epilepsy or convulsions
- suffer from muscle weakness (a disease called myasthenia gravis)

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

##### **Talk to your doctor or pharmacist before taking Methocarbamol if you:**

- are pregnant or thinking of becoming pregnant
- are breastfeeding
- have, or have had, any kidney or liver problems
- 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.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking methocarbamol.

**Children and adolescents**

This medicine is not recommended for use in children and adolescents under 18 years old.

**Other medicines and Methocarbamol**

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Methocarbamol affects the way some other medicines work. Also some medicines can affect the way methocarbamol works.

**If you are taking any of the following medicines, you should tell your doctor or pharmacist as methocarbamol may interact with them:**

- Barbiturates which can be taken for epilepsy or to help you sleep.
- Appetite suppressants to help you lose weight.
- Medicines for stomach upsets or sea-sickness (anti-cholinergics).
- Psychotropic drugs for the treatment of anxiety, depression or other mental illnesses.
- If you are due to have anaesthetic for any reason, tell your doctor or dentist that you are taking methocarbamol.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking methocarbamol.

**Methocarbamol with food, drink or alcohol**

Methocarbamol should be taken with a drink that does not contain alcohol. Do not drink alcohol while you are taking methocarbamol.

**Pregnancy, breast-feeding and fertility**

Do not take this medicine if you are pregnant or might become pregnant unless your doctor tells you to. Contact your doctor if you think you may be pregnant, or are intending to become pregnant.

Do not take this medicine if you are breast-feeding or planning to breast-feed.

No data are available concerning the effect of this medicine on human fertility.

**Driving and using machines:**

Methocarbamol may make you feel sleepy and may affect your ability to drive, operate machinery and carry out other hazardous activities. These activities should therefore be avoided altogether until you are sure you are not affected

**Methocarbamol contains 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.

**3. HOW TO TAKE METHOCARBAMOL**

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

**Dose and administration**

**Adults:** Take TWO tablets with a little water, FOUR times a day. Sometimes a lower dose may be sufficient. You should spread the doses as evenly as possible over a 24-hour period.

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

**Children:** These tablets should not be given to children and adolescents under 18 years old

**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.

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

#### **Duration of treatment**

These tablets are for short-term treatment. Take them for as long as your doctor has recommended, or until you no longer need them to ease the pain. Return any unused tablets to your pharmacist.

#### **If you take more methocarbamol than you should**

It is important to stick to your prescribed dose. If you or someone else takes too much medicine, contact your doctor or nearest hospital emergency department immediately. Always take any medicine left over with you and also the pack, as this will allow easier identification of the medicine.

#### **If you forget to take methocarbamol**

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

#### **If you stop taking methocarbamol**

Keep taking methocarbamol until your doctor tells you to stop.

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

## **4. POSSIBLE SIDE EFFECTS**

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

**STOP taking this medicine and tell your doctor immediately if you experience any of the following rare symptoms:**

- confusion, convulsions, fits, and rash or swelling of the face or neck and shortness of breath which may be a sign of an allergy.

**If you notice any of these symptoms, you should contact your doctor: -**

yellowing of the skin and/or whites of the eyes.

**The levels of your white blood cells may also be reduced which can lead to recurrent:**

- infections
- mouth ulcers

**If any of the following side effects are troublesome, you should tell your doctor:**

- drowsiness, difficulty in sleeping,
- restlessness, anxiety or worry,
- eating disorders

- dizziness,
- memory loss,
- blurred or double vision, rapid or unusual eye movements,
- reddening of the eyes together with nasal stuffiness,
- feeling sick or vomiting,
- heartburn,
- taste disturbance,
- tremor or shakiness, mild muscle incoordination,
- headache,
- fever,
- itching,
- a slow heartbeat,
- flushing,
- fainting or feeling faint,
- low blood pressure,

### **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 **[to be completed during the national phase of the application]**. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE METHOCARBAMOL**

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Do not use methocarbamol after the expiry date, which is stated on the outer carton label and the blister pack. The expiry date refers to the last day of the month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What methocarbamol contains?**

The active substance in your tablet is methocarbamol. Each film-coated tablet contains 750mg of methocarbamol. The other ingredients are:

#### Tablet core:

Sodium Starch Glycolate Type A  
 Starch, Pregelatinised  
 Sodium Lauryl Sulphate  
 Povidone  
 Magnesium Stearate

#### Tablet coating:

Hypromellose  
 Titanium Dioxide  
 Lactose Monohydrate  
 Macrogol  
 Triacetin

**What methocarbamol looks like and contents of the pack**

Methocarbamol 750mg film-coated tablets are white to off-white, slightly curved oblong film-coated tablets with double-sided scoring. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

PVC/PVDC-blisters containing 20, 30, 50 or 100 film-coated tablets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**MA Holder:

HBS Healthcare Limited

Moor Park Avenue

Preston

PR1 6AS

United Kingdom

Manufacturer:

Geryon Pharma

25 Compass West

Liverpool

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