Package leaflet: Information for the patient

Methocarbamol 750 mg film-coated Tablet
for use in adults

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 750 mg film-coated Tablet is and what it is used for

Methocarbamol 750 mg film-coated Tablet contains the active substance methocarbamol. Methocarbamol belongs to a group of medicines called muscle relaxants.

Methocarbamol 750 mg film-coated Tablet is used for symptomatic treatment of painful muscle spasms, especially of the lower back (lumbago).

Methocarbamol 750 mg film-coated Tablet is used in adults.

2. What you need to know before you take Methocarbamol 750 mg film-coated Tablet

Do not take Methocarbamol 750 mg film-coated Tablet,
- if you are allergic to methocarbamol or any of the other ingredients of this medicine listed in section 6.
- if you are in comatose or precomatose states.
- if you have diseases of the central nervous system.
- if you have a pathological muscle weakness (Myasthenia gravis).
- if you have a tendency to epileptic convulsions.

Warnings and precautions
Talk to your doctor or pharmacist before taking Methocarbamol 750 mg film-coated Tablet,
- if you have impaired renal function and / or impaired hepatic function.

Interference with laboratory tests
Methocarbamol may cause color interference with laboratory tests for hydroxyindoleacetic acid (5- HIAA) and vanillin mandelic acid (VMA).

Children and Adolescents
This medicine is not intended for use in children and adolescents, as there is insufficient experience in this population.

Other medicines and Methocarbamol 750 mg film-coated Tablet
Tell your doctor or pharmacist if you are taking/using, have recently taken/used, or might take/use any other medicines.

When Methocarbamol is used concomitantly with centrally acting medicines such as barbiturates, opiate derivatives as well as appetite suppressants, there may be a mutual enhancement of effect.

The effect of anticholinergics, such as atropine, and other psychotropic medicines may be enhanced by methocarbamol.

Methocarbamol may attenuate the effect of pyridostigmine bromide. Therefore, Methocarbamol must not be taken by patients with pathological muscle weakness (myasthenia gravis), especially those treated with pyridostigmine.

Methocarbamol 750 mg film-coated Tablet with alcohol
Consumption of alcohol during treatment with methocarbamol may increase the effect.

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

Pregnancy
There is no experience with the use of methocarbamol during pregnancy. The potential risk to humans is not known. As a precaution, do not take Methocarbamol 750 mg film-coated Tablet during pregnancy.

Breast-feeding
It is not known whether methocarbamol and/or its metabolites pass into breast milk in humans. As a precaution you should not take Methocarbamol 750 mg film-coated Tablet if you are breastfeeding.

Fertility
No data are available on the effect of methocarbamol on fertility in humans.

Driving and using machines
Methocarbamol 750 mg film-coated Tablet may affect your ability to drive and use machines. Before you consider driving a vehicle or using machines, you should take into account your medical condition and the possible side effects of Methocarbamol 750 mg film-coated Tablet. Therefore, you should not perform these activities until you have experienced that you do not have any corresponding side effects, such as dizziness or drowsiness.

Methocarbamol 750 mg film-coated Tablet contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Methocarbamol 750 mg film-coated Tablet contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per mg, that is to say essentially 'sodium-free'.

3. How to take Methocarbamol 750 mg film-coated Tablet

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

Unless otherwise prescribed by your doctor, the recommended dose for adults is 1500 mg methocarbamol (2 film-coated tablet 750 mg each or 1 film-coated tablet 1500 mg), 3 times daily. At the beginning of treatment, a dose of 1500 mg methocarbamol (2 film-coated tablet of 750 mg each, or 1 film-coated tablet 1500 mg), 4 times daily is recommended.

In severe cases, patients may take up to 7500 mg (10 film-coated tablets of 750 mg or 5 film-coated tablet 1500 mg) per day.

Method of administration
The film-coated tablets are for oral use.
Swallow the film-coated tablets with plenty of water.
The score line is only here to help you break the tablet if you have difficulty swallowing it whole.
A bitter after taste should be expected when taking divided tablets.

Duration of treatment
The film-coated tablets should be taken as long as the symptoms of muscle spasms persist, but not longer than 30 days.

If you take more Methocarbamol 750 mg film-coated Tablet than you should
Inform your doctor. He or she will decide on the necessary action

If you forget to take Methocarbamol 750 mg film-coated Tablet
Do not take a double dose to make up for a forgotten dose.

If you stop taking Methocarbamol 750 mg film-coated Tablet
Please inform your doctor if you intend to stop therapy with Methocarbamol 750 mg film-coated Tablet. No particular effects are expected when stopping the use of this medicine.

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.

Possible side effects
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, angioneurotic edema (acute swelling of parts of the tissue or skin), rash, itching, hives, 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, eye twitching, giddiness, tremor, seizure, worsening of vision, double vision, slowed heartbeat, flushing, nausea, and vomiting.
Frequency not known (frequency cannot be estimated based on available data):
Drowsiness, disturbance of coordination, local transient sensory disturbances (mainly in the area of the face, scalp, lips, tongue, hands, fingers or feet), nausea, diarrhea, 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, Website: 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 also provide more information on the safety of this medicine.

5. How to store Methocarbamol 750 mg film-coated Tablet

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 blister after "EXP". The expiry date refers to the last day of the month.

Do not store above 25° 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 film-coated Tablet contains

- The active substance is methocarbamol.
- 1 film-coated tablet contains 750 mg of methocarbamol.
- The other ingredients are:
  Tablet core: maize starch, sodium starch glycolate (type A), povidone K-30, sodium laurilsulfate, stearic acid, magnesium stearate.
  Film coating: lactose monohydrate, hypromellose, macrogol 4000, titanium dioxide (E171).

What Methocarbamol 750 mg film-coated Tablet looks like and contents of the pack

White to off-white capsule shaped, film coated tablets with breakline on both the sides with approximate dimension of 18.90 mm in length, 8.35 mm in width.
The score line is only here to help you break the tablet if you have difficulty swallowing it whole.

Methocarbamol 750 mg film-coated Tablet is available in pack of 8, 10, 96 & 100 film-coated Tablets.
Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

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