Approved Patient Information Leaflet for Medicines for Human Use:

METHOCARBAMOL 750 mg SHANUR

SCHEDULING STATUS: S2

METHOCARBAMOL 750 mg SHANUR film-coated tablets

Methocarbamol

Contains sugar: lactose monohydrate.

Each film-coated tablet contains 5,50 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking METHOCARBAMOL 750 mg SHANUR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Do not share METHOCARBAMOL 750 mg SHANUR with any other person.

What is in this leaflet

1. What METHOCARBAMOL 750 mg SHANUR is and what it is used for
2. What you need to know before you take METHOCARBAMOL 750 mg SHANUR
3. How to take METHOCARBAMOL 750 mg SHANUR
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1. What METHOCARBAMOL 750 mg SHANUR is and what it is used for

Each film-coated tablet contains 750 mg methocarbamol which belongs to a group of medicines called muscle relaxants.

METHOCARBAMOL 750 mg SHANUR is used for the short-term treatment of pain and muscle spasm

caused by injuries such as sprains and strains.

2. What you need to know before you take METHOCARBAMOL 750 mg SHANUR

Do not take METHOCARBAMOL 750 mg SHANUR

- if you are hypersensitive (allergic) to methocarbamol or any of the other ingredients of METHOCARBAMOL 750 mg SHANUR (listed in section 6).
- if you have ever suffered any brain damage or coma.
- if you suffer from epilepsy or convulsions.
- if you suffer from muscle weakness (a disease called myasthenia gravis).

Warnings and precautions

Special care should be taken with METHOCARBAMOL 750 mg SHANUR:

- if you have, or have had, any kidney or liver problems
- if you are having any medical investigations or tests as METHOCARBAMOL 750 mg SHANUR could interfere with the results. Tell your health care provider that you are taking METHOCARBAMOL 750 mg SHANUR before you have the test.

Other medicines and METHOCARBAMOL 750 mg SHANUR

Always tell your health care provider if you are taking any other medicine. This includes all complementary or traditional medicines.

If you are taking any of the following medicines, you should tell your doctor or pharmacist as METHOCARBAMOL 750 mg SHANUR 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 seasickness (anti-cholinergics)
- psychotropic medicines for the treatment of anxiety, depression or other mental illnesses
- if you are due to have anaesthetic for any reason, tell your health care provider or dentist that you

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are taking METHOCARBAMOL 750 mg SHANUR.

METHOCARBAMOL 750 mg SHANUR with food, drink and alcohol

You should avoid drinking alcohol while taking METHOCARBAMOL 750 mg SHANUR.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your health care provider for advice before taking this medicine.

Driving and using machines

METHOCARBAMOL 750 mg SHANUR may make you feel sleepy. Do not drive or operate machinery until you are sure you are not affected.

It is not always possible to predict to what extent METHOCARBAMOL 750 mg SHANUR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which METHOCARBAMOL 750 mg SHANUR affects them.

METHOCARBAMOL 750 mg SHANUR contains lactose

Contains sugar: lactose monohydrate 5,50 mg.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Sodium: This medication contains less than 1 mmol sodium (23 mg) per tablet, that is to say it is essentially 'sodium-free'.

3. How to take METHOCARBAMOL 750 mg SHANUR

Do not share medicines prescribed for you with any other person.

Always take METHOCARBAMOL 750 mg SHANUR exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The following table provides the test and specifications for the approximate dimensions of the tablets:

Test	Specification
Shape	Capsule shape
Thickness (mm)	6,60 ± 0,4 mm (6,20 mm -7,00 mm)
Length (mm)	19 mm
Width (mm)	8 mm

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.

Maintenance dosage: 1 tablet every four hours or 2 tablets three times a day.

Six grams a day are recommended for the first 48 to 72 hours of treatment.

(For severe conditions, 8 grams a day may be administered). Thereafter, the dosage can usually be reduced to approximately 4 grams a day.

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.

Liver impairment

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

Duration of administration

These tablets are for short-term treatment. Take them for as long as your health care provider has recommended, or until you no longer need them to ease the pain.

Method of administration

METHOCARBAMOL 750 mg SHANUR is for oral administration.

If you take more METHOCARBAMOL 750 mg SHANUR than you should

In the event of overdosage, consult your health care provider. If neither is available, contact the nearest hospital or poison centre.

If you forget to take METHOCARBAMOL 750 mg SHANUR

If you forget to take a dose, leave that dose out completely. Take your next dose at the right time and continue as before. Do not take a double dose to make up for the forgotten dose.

4. Possible side effects

METHOCARBAMOL 750 mg SHANUR can have side effects.

Not all side effects reported for METHOCARBAMOL 750 mg SHANUR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking METHOCARBAMOL 750 mg SHANUR, please consult your health care provider for advice.

If any of the following happens, stop taking METHOCARBAMOL 750 mg SHANUR and tell your health care provider immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in

swallowing or breathing

- rash or itching
- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to METHOCARBAMOL 750 mg SHANUR. You may need urgent medical attention or hospitalisation.

Less frequent side effects:

- leucopenia (low level of white blood cells)
- vertigo, tremor, seizures (including grand mal).

Side effects with frequency unknown:

- angioedema (swelling under the skin), anaphylactic reaction, fever
- bradycardia (slow heart rate)
- hypotension, syncope, flushing
- dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting, metallic taste
- anorexia
- restlessness, anxiety, amnesia, confusion, diplopia, dizziness or light-headedness, drowsiness, insomnia, mild muscular incoordination, nystagmus, headache
- metallic taste, pruritus, rash, urticaria
- blurred vision, conjunctivitis with nasal congestion
- lassitude.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your health care provider. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA

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website. By reporting side effects, you can help provide more information on the safety of METHOCARBAMOL 750 mg SHANUR.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@shanur.co.za.

5. How to store METHOCARBAMOL 750 mg SHANUR

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the blister packs in the outer carton until required for use.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What METHOCARBAMOL 750 mg SHANUR contains

The active substance is Methocarbamol.

METHOCARBAMOL 750 mg SHANUR film-coated tablet:

Each film-coated tablet contains 750 mg methocarbamol.

White to off-white slightly curved oblong film coated tablets with double sided scored.

The other ingredients are magnesium stearate, opadry II white, povidone, pregelatinised starch, sodium lauryl sulphate, sodium starch glycolate type A, hypromellose, lactose monohydrate, macrogol, titanium dioxide and triacetin.

Composition of Opadry II White 32G580001

HPMC2910/Hypromellose E464

Lactose monohydrate

Macrogol/PEG E1521

Titanium dioxide E171

Triacetin

What METHOCARBAMOL 750 mg SHANUR looks like and contents of the pack

METHOCARBAMOL 750 mg SHANUR are packed in PVC/PVDC white opaque blister packs.

The blisters are packed into cardboard cartons in pack sizes of 10’s, 20’s and 50’s.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information

Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information for this medicine is available on the following URL: https://shanur.co.za/product-info/

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