SCHEDULING STATUS:

S2

ROBAXIN (methocarbamol 500 mg/tablet)

ROBAXIN-750 (methocarbamol 750 mg/tablet)

Sugar free

Read all of this leaflet carefully because it contains important information for you.

ROBAXIN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ROBAXIN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ROBAXIN with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What ROBAXIN is and what it is used for

2. What you need to know before you use ROBAXIN

3. How to use ROBAXIN

4. Possible side effects

5. How to store ROBAXIN

6. Contents of the pack and other information

1. What ROBAXIN is and what it is used for

Muscle relaxant. **ROBAXIN** is indicated as an adjunct to rest, physical therapy, and other

measures for the relief of muscle spasm associated with acute, painful, musculoskeletal conditions.

2. What you need to know before you take ROBAXIN

Do not take ROBAXIN if:

- If you are hypersensitive (allergic) to Methocarbamol or any of the other ingredients of ROBAXIN and ROBAXIN -750.
- ROBAXIN is contraindicated in hypersensitive patients, in CNS depressed, coma or pre-coma states, brain damage, myasthenia gravis, or in patients with a history of epilepsy.

You should not use ROBAXIN if you have poorly working kidneys or liver problems.

Safety and effectiveness in children below the age of 12 years has not been established.

Warnings and precautions

Take special care with ROBAXIN

ROBAXIN may cause colour interference and falsely increase values in certain screening tests for 5 - hydroxyindoleacetic acid (5-HIAA) and vanilylmandelic acid (VMA).

Other medicines and ROBAXIN

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

Use ROBAXIN with caution if you are taking any of the following medicines:

- CNS depressants and stimulants including alcohol, barbiturates, anaesthetics and appetite suppressants, as they may increase the effects of ROBAXIN.

- anorectics, anticholinergics (e.g. atropine), antimuscarinics and some psychotropic agents as their effects may be increased.

ROBAXIN may cause pyridostigmine to be less effective.

ROBAXIN with food, drink and alcohol

No data available

Pregnancy and breastfeeding and fertility

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

ROBAXIN should not be used in women who are or may become pregnant.

It is not known whether this medicine is secreted in human milk.

The safety of this preparation in pregnancy and lactation has not been established

Driving and using machines

ROBAXIN may impair concentration: Until your response to ROBAXIN's side-effects have stabilised, you should not drive motor vehicles or operate dangerous machinery.

It is not always possible to predict to what extent ROBAXIN 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 ROBAXIN affects them.

3. How to take ROBAXIN

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

Always take ROBAXIN exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

ROBAXIN: Adults

Initial dosage: 3 tablets four times a day.

Maintenance dosage: 2 tablets four times a day.

ROBAXIN-750: Adults

Initial dosage: 2 tablets four times a day.

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: Half the maximum recommended adult daily dose or less, may be sufficient to produce a therapeutic response in the elderly.

Children: Not recommended.

If you take more ROBAXIN than you should

You may feel very drowsy.

In the event of an overdosage, consult your doctor or pharmacist.

If neither is available, contact the nearest hospital or poison centre.

If you forget to take ROBAXIN

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ROBAXIN can have side effects.

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

Metabolism and nutrition disorders:

Has been reported but frequency is unknown: loss of appetite

Eye disorders:

Has been reported but frequency is unknown: blurred vision

Nervous system disorders:

Has been reported but frequency is unknown: light-headedness, dizziness, drowsiness, headache

Rare: vertigo, tremor, convulsions

Gastrointestinal disorders:

Has been reported but frequency is unknown: nausea, vomiting

Immune system disorders:

Has been reported but frequency is unknown: itchy rash, rash, swelling of the skin or mucous membranes, pink eye with nasal congestion

General disorders and administration site conditions:

Has been reported but frequency is unknown: fever, lassitude

Psychiatric disorders:

Rare: restlessness, anxiety, confusion

Blood and lymphatic system disorders:

Rare: reduction in the number of white blood cells in the blood

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ROBAXIN.

5. How to store ROBAXIN

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light and moisture.

Do not use after the expiry date stated on the label.

Return all unused medicines to your pharmacist. Do not dispose of unused medicine in drains or sewage systems (e.g. toilets).

6. Contents of the pack and other information

What ROBAXIN contains

The active substance is Methocarbamol.

ROBAXIN is available as a 500 mg tablet and a 750 mg tablet.

Each ROBAXIN tablet contains 500 mg methocarbamol.

Each ROBAXIN-750 tablet contains 750 mg methocarbamol.

The other ingredients are:

magnesium stearate, maize starch, opadry orange 85F230056 (500 mg tablet), opadry orange 85F230055 (750 mg tablet), povidone, sodium lauryl sulphate, sodium starch glycollate and stearic acid.

What ROBAXIN looks like and contents of the pack

ROBAXIN: A light orange, round, bisected, film coated tablet, one side is debossed "ROBAXIN" and the other side is bisected.

ROBAXIN -750: An orange, capsule-shaped, film coated tablet, one side is debossed "ROBAXIN 750" and plain on the other side.

ROBAXIN and ROBAXIN-750 are available in PVC/aluminium blister packs of 50 tablets. Ten tablets per blister, 5 blister strips per unit carton. PVC/aluminium blister packs of 20 tablets. Ten tablets per blister, 2 blister strips per unit carton. They are also available in white Polypropylene securitainers with LDPE caps in a pack size of 100 tablets.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

Not applicable

Application number

ROBAXIN: B1554 (Act 101/1965)

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