Approved Patient Information Leaflet for Medicines for Human Use:

MYLOSPAS

SCHEDULING STATUS: S2

MYLOSPAS 750 mg film-coated tablets

Methocarbamol

Contains sugar:

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

Read all of this leaflet carefully before you start taking MYLOSPAS

- 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 MYLOSPAS with any other person.

What is in this leaflet

1. What MYLOSPAS is and what it is used for
2. What you need to know before you take MYLOSPAS
3. How to take MYLOSPAS
4. Possible side effects
5. How to store MYLOSPAS
6. Contents of the pack and other information

1. What MYLOSPAS 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.

MYLOSPAS 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 MYLOSPAS

Do not take MYLOSPAS:

- if you are hypersensitive (allergic) to methocarbamol or any of the other ingredients of MYLOSPAS (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 MYLOSPAS:

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

Other medicines and MYLOSPAS

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 MYLOSPAS 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 are taking MYLOSPAS.

MYLOSPAS with food, drink and alcohol

You should avoid drinking alcohol while taking MYLOSPAS.

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

MYLOSPAS 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 MYLOSPAS 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 MYLOSPAS affects them.

MYLOSPAS 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.

Austell Pharmaceuticals (Pty) Ltd, 550765, MYLOSPAS, Film-coated Tablets, 750 mg
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 MYLOSPAS

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

Always take MYLOSPAS 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

MYLOSPAS is for oral administration.

If you take more MYLOSPAS 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 MYLOSPAS

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

MYLOSPAS can have side effects.

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

If any of the following happens, stop taking MYLOSPAS 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 MYLOSPAS. 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 "**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 MYLOSPAS.

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

5. How to store MYLOSPAS

Store all medicines out of reach of children

Store at or below 25 ºC.

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 MYLOSPAS contains

The active substance is Methocarbamol.

Austell Pharmaceuticals (Pty) Ltd, 550765, MYLOSPAS, Film-coated Tablets, 750 mg

MYLOSPAS 750 mg 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, Triacetin

Composition of Opadry II White 32G580001

HPMC2910/Hypromellose E464

Lactose monohydrate

Macrogol/PEG E1521

Titanium dioxide E171

Triacetin

What MYLOSPAS looks like and contents of the pack

MYLOSPAS 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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Austell Pharmaceuticals (Pty) Ltd, 550765, MYLOSPAS, Film-coated Tablets, 750 mg

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This leaflet was last revised in

07 November 2023

Registration number

MYLOSPAS: 55/2.10/0765

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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