Approved Professional Information for Medicines for Human Use:

MYLOSPAS

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

MYLOSPAS 750 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

MYLOSPAS 750 mg film-coated tablets

Each film-coated tablet contains 750 mg methocarbamol.

Contains sugar: lactose monohydrate 5,50 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.

MYLOSPAS 750 mg film-coated tablets

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

MYLOSPAS (methocarbamol) is indicated as an adjunct to rest, physical therapy, and other measures for the relief of muscle spasm associated with acute, painful, musculoskeletal conditions.

4.2 Posology and method of administration

Posology

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.

Special populations

Elderly population

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

Paediatric population

Not recommended.

Method of administration

MYLOSPAS is for oral administration.

4.3 Contraindications

- Hypersensitivity to methocarbamol or to any of the excipients listed in section 6.1 as in MYLOSPAS.
- CNS depressed, coma or pre-coma states

- Brain damage
- Myasthenia gravis
- Patients with a history of epilepsy

4.4 Special warnings and precautions for use

MYLOSPAS should be used with caution in patients with renal and hepatic insufficiency.

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

Excipients: lactose intolerance

This medicine contains lactose:

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

4.5 Interaction with other medicines and other forms of interaction

MYLOSPAS may potentiate the effects of other central nervous system depressants and stimulants including alcohol, barbiturates, anaesthetics and appetite suppressants. The effects of anticholinergics, e.g. atropine and some psychotropic medicines, may be potentiated by methocarbamol as in MYLOSPAS. Methocarbamol as in MYLOSPAS may inhibit the effect of pyridostigmine bromide. Little is known about the possibility of interactions with other medicines.

Methocarbamol as in MYLOSPAS may cause colour interference in certain screening tests for 5-hydroxyindolacetic acid (5-HIAA) using nitrosoaphthol reagent and in screening tests for urinary vanillymandelic acid (VMA) using the Gitlow method.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safe use of methocarbamol as in MYLOSPAS has not been established with regard to possible adverse effects upon foetal development.

There have been reports of foetal and congenital abnormalities following in utero exposure to methocarbamol as in MYLOSPAS.

Therefore, MYLOSPAS should not be used in women who are or may become pregnant and particularly during early pregnancy.

Breastfeeding

Methocarbamol and/or its metabolites are excreted in the milk of dogs: however, it is not known whether methocarbamol or its metabolites are excreted in human milk. Safe use of MYLOSPAS in breastfeeding has not been established.

Fertility

Animal reproductive studies have not been conducted with methocarbamol as in MYLOSPAS. It is also not known whether methocarbamol as in MYLOSPAS can affect reproduction capacity.

4.7 Effects on ability to drive and use machines

This product may cause drowsiness and patients receiving it should not drive nor operate machinery unless their physical and mental capabilities remain unaffected - especially if other medication capable of causing drowsiness is also being taken.

4.8 Undesirable effects

Adverse reactions reported coincident with the administration of methocarbamol include

Immune system disorders:

Frequency unknown: angioedema. anaphylactic reaction. fever

Cardiac disorders:

Frequency unknown: Bradycardia.

Vascular disorders: hypotension. syncope. Flushing

Gastrointestinal disorders:

Frequency unknown: Dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting, metallic taste.

Metabolism and nutritional disorders:

Frequency unknown: anorexia

Blood and lymphatic system:

Less frequent: Leucopenia.

Nervous system:

Frequency unknown: Restlessness, anxiety, amnesia, confusion, diplopia, dizziness or light-headedness, drowsiness, insomnia, mild muscular incoordination, nystagmus, headache.

Less frequent: vertigo, tremor, seizures (including grand mal)

Skin and subcutaneous tissue disorders: metallic taste, pruritus, rash, urticaria.

Eye disorders:

Frequency unknown: blurred vision, conjunctivitis with nasal congestion.

General disorders and administration site conditions:

Frequency unknown: Lassitude

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions 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

Suspected adverse reactions can also be reported directly to the HCR via medsafety@austell.co.za

4.9 Overdose

Limited information is available on the acute toxicity of methocarbamol as in MYLOSPAS. Overdose of methocarbamol as in MYLOSPAS is frequently in conjunction with alcohol or other CNS depressants and includes the following symptoms: nausea, drowsiness, blurred vision, hypotension, seizures and coma. One adult survived the deliberate ingestion of 22 to 30 grams of methocarbamol without serious toxicity. Another adult survived a dose of 30 to 50 grams. The principal symptom in both cases was extreme drowsiness. Treatment was symptomatic and recovery was uneventful. However, there have been cases of fatal overdose.

Management of overdose includes symptomatic and supportive treatment. Supportive measures include maintenance of an adequate airway, monitoring urinary output and vital signs, and administration of intravenous fluids if necessary. The usefulness of haemodialysis in managing overdose is unknown.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification:

Category and Class: A.2.10 Centrally acting muscle relaxant.

Pharmacotherapeutic group: Muscle relaxants, centrally acting agents; Carbamic acid esters

ATC Code: M03BA03

Mechanism of action

The mechanism of action of methocarbamol in humans has not been established but may be due to general central nervous system (CNS) depression. Animal studies indicate that methocarbamol is a skeletal muscle relaxant with a selective action on

the central nervous system, specifically the internuncial neurones. It relaxes hypertonic muscle and lowers response to sensory stimuli. It has no direct action on the contractile mechanism of striated muscle, the motor end plate, or the nerve fibre.

5.2 Pharmacokinetic properties

Methocarbamol Is rapidly and almost completely absorbed from the gastrointestinal tract following oral administration. Its effects occur within about half an hour of an oral dose. Its plasma half-life is reported to be about 1 - 2 hours.

It is metabolised by dealkylation and hydroxylation and is excreted in urine primarily as the glucuronide and sulphate conjugate of its metabolites. A small amount is excreted in faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate

Opadry II white 32G580001

Povidone (K29/32)

Pregelatinised starch

Sodium Lauryl sulphate

Sodium starch Glycolate Type A

Composition of Opadry II White 32G580001

HPMC2910/Hypromellose E464

Lactose monohydrate

Macrogol/PEG E1521

Titanium dioxide E171

Triacetin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25 ^{o}C.

6.5 Nature and contents of container

MYLOSPAS 750 mg film-coated tablets 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.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd

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8. REGISTRATION NUMBER

MYLOSPAS: 55/2.10/0765

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07 November 2023

10. DATE OF REVISION OF THE TEXT