For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Rx

Myospaz®

Chlorzoxazone and Paracetamol Tablets

Muscle Relaxant /Analgesic

COMPOSITION :
Each uncoated tablet contains :
Chlorzoxazone USP : 250 mg
Paracetamol BP : 500 mg

ACTION :
In Myospaz, the combined analgesic effect of paracetamol and the muscle relaxant action of chlorzoxazone provides in-depth relief from pain associated with skeletal muscle spasm.

Paracetamol possesses analgesic and antipyretic actions similar to those of the salicylates. Analgesia is mediated peripherally and also centrally.

Chlorzoxazone is an orally effective muscle relaxant. Muscle relaxation is not due to direct action on the muscle itself, rather the site of action of chlorzoxazone is probably in the subcortical centers, brain stem and spinal polysynaptic pathways. In therapeutic doses in man, chlorzoxazone does not interfere with normal voluntary movement and has no direct effect on smooth muscle. The peripheral sensory system is not affected, nor is the cerebral cortex to any extent, for there is no impairment of thought processes, clouding of consciousness or drowsiness in most cases.

PHARMACOKINETICS:
Chlorzoxazone is rapidly and completely absorbed after oral administration. It is metabolized in the liver, mainly to 6-hydroxychlorzoxazone, and excreted in the urine primarily as the glucuronide. The elimination half-life of chlorzoxazone is about one hour.

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma- protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. Paracetamol is metabolized primarily in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5 % is excreted as unchanged paracetamol. A minor hydroxylated metabolite (*N* – acetyl – *p* – benzoquinoneimine) which is usually produced in very small amounts by mixed-function oxidases in the liver and kidney and which is usually detoxified by conjugation with glutathione may accumulate following paracetamol overdose and cause tissue damage. The elimination half life varies from about 1 to 3 hours.

INDICATIONS :
For the relief of pain and muscle spasm associated with inflammatory and degenerative processes; fibrositis, myositis, bursitis, tenosynovitis, torticollis, osteoarthritis, trauma, intervertebral disc syndrome, lumbago, sacroiliac pain, muscular and tendinous sprains, contusions, postoperative myalgia, post tooth extraction.

CONTRAINDICATIONS :
Sensitivity to paracetamol or chlorzoxazone.

WARNINGS :
Should drowsiness occur, the dose should be reduced. As with other CNS-acting drugs, patients receiving chlorzoxazone should be warned against performing potentially hazardous tasks which require complete mental alertness, such as operating a motor vehicle or dangerous machinery. Patients should also be warned of the possible additive effects which may occur when the drug is taken with alcohol or other CNS-acting drugs.

PRECAUTIONS :
Usage in Pregnancy and Lactation : Safe use of this preparation in pregnancy or lactation has not been established as no animal reproduction studies have been performed ; therefore, usage in pregnancy and lactation requires that the potential benefit be weighed against possible hazards.

ADVERSE REACTIONS :
Adverse effects reported to occur with chlorzoxazone include :
GI : nausea, vomiting, epigastric distress
CNS : drowsiness, dizziness, lightheadedness, malaise
Skin : Allergic skin rashes (rarely)
Hepatic : hepatitis
Miscellaneous : urine discoloration
When taken in recommended doses, paracetamol is usually free from side effects. Skin reactions, such as urticaria, have been described rarely.

DOSAGE AND ADMINISTRATION :
Adult : 1 tablet 3 or 4 times a day, according to the intensity of pain and spasm.
Children : 7 to 12 years : 1/2 to 1 tablet 3 or 4 times a day or according to the physician's directions.
As improvement occurs, dosage can usually be reduced.

PATIENT INFORMATION :
Take after food or meals if GI upset occurs. Notify physician of skin rash or itching.
May cause drowsiness, dizziness or lightheadedness. Observe caution while driving or performing other tasks requiring alertness. Avoid alcohol and other CNS depressants.
Medication may discolor urine to orange or purple-red.

OVERDOSAGE :
Serious toxicity is rare following administration of recommended doses. However, when taken in large amounts, hepatic necrosis may result. Clinical and laboratory evidence of hepatotoxicity may be delayed for up to a week.

PRESENTATION :
Box of 100 tablets (10 strips of 10 tablets each).

STORAGE :
Store protected from light and moisture at a temperature not exceeding 30°C.

® : Registered Trade Mark in India

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