

SUMMARY PRODUCT CHARACTERISTICS

1. Name of the medicinal product

MYOCOR

2. Qualitative and quantitative composition

Each uncoated tablet contains:

Chlorzoxazone USP	500 mg
Paracetamol BP	325 mg
Excipients	q.s

3. Pharmaceutical form

Oral Dosage form: Oral uncoated Tablets

White coloured, oblong shaped, uncoated tablets having breakline on one side and plain on other side.

4. Clinical particulars

4.1 Therapeutic 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.

4.2 Posology and method of administration

Adult: 1 or 2 tablets 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.

4.3 Contraindications

Sensitivity to paracetamol or chlorzoxazone.

4.4 Special warnings and precautions for use Diclofenac :

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 hazardous.

4.5 Interaction with other medicinal products and other forms of interaction

Drug Interaction		
Precipitant Drug	Object Drug*	Description

Alcohol, ethyl	APAP	↑	Hepatotoxicity has occurred in chronic alcoholics following various dose levels (moderate to excessive) of acetaminophen.
Anticholinergics	APAP	↓	The onset of acetaminophen effect may be delayed or decreased slightly, but the ultimate pharmacological effect is not significantly affected by anticholinergics.
Beta blockers, propranolol	APAP	↑	Propranolol appears to inhibit the enzyme systems responsible for the glucuronidation and oxidation of acetaminophen. Therefore, the pharmacological effects of acetaminophen may be increased.
Charcoal, activated	APAP	↓	Reduces acetaminophen absorption when administered as soon as possible after overdose.
Contraceptives	APAP	↓	Increase in glucuronidation resulting in increased plasma clearance and a decreased half-life of acetaminophen.
Probenecid	APAP	↑	Probenecid may increase the therapeutic effectiveness of acetaminophen slightly.
APAP	Lamotrigine	↓	Serum lamotrigine concentrations may be reduced producing a decrease in therapeutic effects.
APAP	Loop diuretics	↓	The effects of the loop diuretics may be decreased because APAP may decrease renal prostaglandin excretion and decrease plasma renin activity.
APAP	Zidovudine	↓	The pharmacologic effects of Zidovudine may be decreased because of enhanced non-hepatic or renal clearance of Zidovudine.

4.6 Fertility, 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 hazardous.

4.7 Effects on ability to drive and use machines

May cause drowsiness, dizziness or lightheadedness. Observe caution while driving or performing other tasks requiring alertness. Avoid alcohol and other CNS depressants

4.8 Undesirable effects

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.

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

4.9 Overdose Diclofenac Symptoms :

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.

5. Pharmacological properties

5.1 Pharmacodynamic properties Diclofenac

In Mayocor, 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.

5.2 Pharmacokinetic properties Diclofenac

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.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical particulars

6.1 List of excipients

Chlorzoxazone

Paracetamol

Maize Starch

Lactose Monohydrate

Microcrystalline Cellulose

Maize Starch

Purified Talc

Magnesium Stearate

Crosscarmellose Sodium

Colloidal Silica Dioxide

Kyron-T 314

6.2 Incompatibilities

None known.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Aluminium – Aluminium Blister Pack

10 Tablets are blister packed with Aluminium – Aluminium foil; such 2 blister is packed in one carton box along with package leaflet.

Pack size: 2 x 10 Tablets in one carton box along with packing leaflet.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses

Marketing Authorization

Signature Healthcare Limited.

The Eco green Business Center (Tilisi)

Off A104 Nairobi -Nakuru Highway Ngecha Chunga Mali Road

P.O. Box 66172-00800, Nairobi.

Manufacturing Site

TNS PHARMA PVT LTD

(A Subsidiary of Trident Lifeline Limited)

Plot No. 4232, Road No. 42, Sachin GIDC, Surat-394230, Gujarat, India.

8. Marketing Authorization Number

CTD13445

9. Date of First Registration

14/05/2026

10. Date of revision of the text

14/05/2026