SUMMARY PRODUCT CHARACTERISTICS

1. Name of the medicinal product :

MYOXAN

2. Qualitative and Quantitative composition:

Composition:

Each hard gelatin capsule contains:

Chlorzoxazone USP ..... 250 mg

Paracetamol BP ..... 300 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form:

Capsules for Oral Administration.

4. Clinical Particulars:

4.1 Therapeutic indications

- Sprains & strains
- Traumatic muscle spasm
- Reflex muscle spasm associated with rheumatic diseases
- Lumbago
- Myalgia
- Tension headache
- Torticollis
- Cervical root syndrome

4.2 Posology and method of administration

Unless otherwise prescribed by the physician, the dose is 1 to 2 capsules three times daily after meals, according to the severity of the case.

Method of administration

For oral administration only

4.3 Contraindications

Hypersensitivity to Chlorzoxazone/Paracetamol is a contraindication. In addition, Chlorzoxazone / Paracetamol should not be used if you have the following conditions:

- Hepatic impairment
- Hypersensitivity

4.4 Special warnings and precautions for use

Chlorzoxazone should not be given to patients with impaired liver functions and should be discontinued if signs of liver damage occur.

4.5 Interaction with other medicinal products and other forms of interaction

Use of other drugs or over the counter products at the same time, the effects of Chlorzoxazone / Paracetamol may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions.

Chlorzoxazone/Paracetamol may interact with the following drugs and products:

Alcohol, Alprazolam, Atorvastatin, Cetirizine, Codeine, Diazepam, Diphenhydramine, Esomeprazole, Interfere with certain laboratory tests, Juxtapid mipomersen, Ketoconazole, Leflunomide, Muscle Relaxants, Prilocaine, Sedatives, Teriflunomide, Topiramate, Zolpidem

4.6 Fertility, pregnancy and lactation

Not recommended during pregnancy or lactation since safety in pregnant women or nursing mothers has not been established.

4.7 Effects on ability to drive and use machines

If you experience drowsiness, dizziness, hypotension or a headache as side-effects when using Chlorzoxazone / Paracetamol medicine then it may not be safe to drive a vehicle or operate heavy machinery.

4.8 Undesirable effects

The most commonly reported side-effects of Chlorzoxazone/ Paracetamol are gastrointestinal bleeding, drowsiness, dizziness, lightheadedness, malaise, and skin rashes.

The following is a list of possible side effects that may occur from the use of Chlorzoxazone / Paracetamol. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious.

Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

Gastrointestinal bleeding, Drowsiness, Dizziness, Lightheadedness, Malaise, Skin rashes, Angioneurotic edema, Anaphylactic reactions, Feeling of sickness, Skin reddening, Allergic reactions, Shortness of breath, Swollen facial features, Liver damage, Abnormalities of blood cells, Nausea, Rashes, Liver toxicity, Less white blood cells, Acute renal tubular necrosis, Blood dyscrasias

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

4.9 Overdose

Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of Chlorzoxazone / Paracetamol, please go to the emergency department of the closest hospital or nursing home.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Paracetamol has analgesic and antipyretic action.

It is more active on cyclo-oxygenase enzyme in brain. Peripherally it is a poor inhibitor of prostaglandin synthesis.

Analgesic action: Paracetamol raises the pain threshold and produces analgesic effect.

Antipyretic action: Paracetamol lowers fever by direct action on the thermoregulatory centre in the Hypothalamus and block the effects of endogenous pyrogen.

This muscle relaxant works by blocking nerve impulses (or pain sensations) that are sent to your brain. It inhibits degranulation of mast cells, subsequently preventing the release of histamine and slow-reacting substance of anaphylaxis (SRS-A), mediators of type I allergic reactions. It may also reduce the release of inflammatory leukotrienes. Chlorzoxazone may act by inhibiting calcium influx.

5.2 Pharmacokinetic properties

Paracetamol:

Absorption: Paracetamol is rapidly and completely absorbed after oral administration.

Distribution: It is distributed mostly in the body in unbound form.

Metabolism: It is extensively metabolised in the liver.

Excretion: Excreted in the urine.

Onset of Action: 30 - 60 minutes

Duration of Action: 6 hours

Half Life: 1-4 hours

Chlorzoxazone:

Absorption- Rapidly and completely absorbed after oral administration.

Distribution- Widely distributed in the body.

Metabolism- It is metabolized in the liver to its metabolites by glucoronide conjugation.

Excretion- It is excreted through urine.

Onset of Action: 1 hr after oral administration

Duration of Action: 3 to 4 hrs

5.3 Preclinical safety data

No preclinical data available

6. Pharmaceutical Particulars:

6.1 List of excipients

Sodium starch Glycolate Type A

Pregelatinized starch

Purified Talc

Povidone K 30 (PVP K 30)

Magnesium stearate

Empty hard gelatin capsule size “0” Black / Violet

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30ºC

6.5 Nature and contents of container

2 x 10 Alu-PVC Blister: 10 capsules packed in an ALU-PVC blister, such two Blisters are packed in a printed carton along with insert.

6.6 Special precautions for disposal and other handling

No special instructions for use/handling.

7. Marketing Authorization Holder:

Ratnamani Healthcare private Ltd

8. Marketing Authorization Number

H2022/CTD10028/16080

9. Date of first Authorization

-

10. Date of revision of text:

1/11/2025