

Relaxon™ Capsules

chlorzoxazone 250 mg, paracetamol 300 mg

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Relaxon™ is and what it is used for
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1. What Relaxon™ is and what it is used for

Chlorzoxazone is a centrally acting skeletal muscle relaxant. It acts primarily at the spinal cord level and subcortical areas of the brain where it inhibits multisynaptic reflex areas involved in producing and maintaining skeletal muscle spasm of varied etiology. This results in reduced skeletal muscle spasm. Relief of pain and increased mobility of involved muscles.

Paracetamol is analgesic and antipyretic. It is as potent as aspirin in inhibiting prostaglandin synthesis in the CNS. The analgesic action of paracetamol adds to that which results secondarily from muscle relaxation.

Relaxon™ capsule offers quick relief of pain and restores mobility even in severe painful spasms of skeletal muscles.

Therapeutic indications:

Relaxon™ capsules is indicated for the relief of severe skeletal muscle spasm associated with acute painful musculoskeletal conditions as:

- Low back pain.
- Cervical root and disc syndromes.
- Sprains and Strains.
- Myalgias.
- Torticollis.
- Tension headaches.
- Traumatic muscle injuries and fibrosis.

2. Before you take Relaxon™**Do not take Relaxon™**

- Relaxon™ capsule is contraindicated with known hypersensitivity to any components of the preparation.
- Avoid in patients with liver disease.

Take special care with Relaxon™

Serious (including Fatal) hepatocellular toxicity (as it has been reported rarely in patients receiving chlorzoxazone.)

The mechanism is unknown but appears to be idiosyncratic and unpredictable. Factors predisposing patients to this rare event are not known. Patients should be instructed to report early signs and/or symptoms of hepatotoxicity such as fever, rash, anorexia, nausea, vomiting, fatigue, right upper quadrant pain, dark urine, or jaundice.

1. Paracetamol (acetaminophen) has been associated with a risk of rare but serious skin reaction, known as Stevens-johnson syndrome, toxic epidermal necrolysis, and generalized exanthematous pustulosis, can be fatal. (Reddening of the skin, rash, blisters and detachment of the upper surface of the skin).

2. These reactions can occur with first-time use of paracetamol (acetaminophen) or at any time while it is being taken.

3. These reactions can occur even if you have taken paracetamol (acetaminophen) in the past without any problems.

4. If you have had a serious skin reaction with paracetamol (acetaminophen), do not take it or any products containing paracetamol (acetaminophen) again.

Chlorzoxazone should be discontinued immediately and a physician consulted if any of these signs or symptoms develops. Chlorzoxazone use should be discontinued if a patient develops abnormal liver enzymes (e.g. AST, ALT, Alkaline phosphatase and bilirubin). The concomitant use of alcohol or other central nervous system depressants have an additive effect.

If any signs or symptoms suggestive of liver dysfunction are observed, the medicine should be discontinued. Dosage in excess of the recommended ones may cause severe liver damage.

"This product contains tartrazine which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of tartrazine sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity."

Patients suffering from kidney disease should take this medicine under medical supervision.

Using other medicines, herbal or dietary supplements

Alcohol and other CNS depressants: They cause drowsiness that may be additive to that induced by chlorzoxazone. They also may increase the potential of hepatotoxicity of paracetamol.

Using Relaxon™ with food and drink

Meals have no influence on Relaxon™.

Pregnancy and breast-feeding

Safety of chlorzoxazone during pregnancy or lactation has not been established.

Use only when clearly needed and when the potential benefits outweigh the potential hazards.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Relaxon™ should not be taken for drivers (as chlorzoxazone causes drowsiness).

3. How to take Relaxon™

Always take Relaxon™ exactly as your doctor has told you. You should check with your doctor if you are not sure.

The usual adult dosage is two capsules to be taken 3 times daily.

4. Possible side effects

Like all medicines, Relaxon™ can cause side effects, although not everybody gets them.

- Occasional GI disturbances, dizziness, nausea, lightheadedness or drowsiness, malaise or over stimulation may be noted.

- Rarely, a patient may note discoloration of urine resulting from a phenolic metabolite of chlorzoxazone.

- Adverse events of paracetamol are rare and usually mild, although haematologic reactions including thrombocytopenia, leucopenia, neutropenia and agranulocytosis have been reported.

- Skin rashes, and other hypersensitivity occur occasionally.

- Prolonged excessive use or abuse of paracetamol can produce nephropathy.

- Even patients who exceeded the recommended doses, pancreatitis associated with paracetamol was rare.

- Ingestion of 15g of paracetamol may cause hepatocellular necrosis and less often, renal necrosis.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Relaxon™

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use Relaxon™ after the expiry date which is stated on the carton.

Do not use Relaxon™ if you notice change in medicine color or odour.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6. Further information**What Relaxon™ contains**

Active ingredients are: Chlorzoxazone 250mg & Paracetamol 300mg.

Inactive ingredients are colloidal silicon dioxide, croscopolidone, magnesium stearate, sodium lauryl sulphate, titanium dioxide, allura red, tartrazine and gelatin.

What Relaxon™ looks like and contents of the pack

Orange opaque cap and white opaque body, hard gelatin capsules, printed with 'Jamjoom' on cap and 'Re 1' on body in black, filled with white to off white homogenous granules.

Relaxon™ available in pack containing three blisters of 10 capsules each.

Marketing Authorisation Holder and Manufacturer

Jamjoom Pharmaceuticals Co., Jeddah, Saudi Arabia.

Tel: +966-12-6081111. Fax: +966-12-6081222

Website: www.jamjoompharma.com

To report any side effect(s):

- Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

Fax: +966-11-205-7662, Call NPC at +966-11-2038222,

Exts: 2317-2356-2353-2354-2334-2340.

Toll free phone: 8002490000

E-mail: npc.drug@sfd.gov.sa

Website: www.sfd.gov.sa/npc

- Other GCC States:

– Please contact the relevant competent authority.


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THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists

 **General Medicine**

Relaxon™ is a quality product manufactured by:

 **جمجوم فارما**
Jamjoom Pharma

P.O.Box 6267 Jeddah - 21442- Saudi Arabia

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