Lagaflex®

(Carisoprodol 300mg and Paracetamol 250mg)

Skeletal Muscle Relaxant

Composition:
Each tablet contains Carisoprodol 300 mg and Paracetamol 250 mg.

Description:
Carisoprodol with its skeletal muscle relaxant property eliminates stiffness in muscles and joints. Paracetamol, a known non-salicylate analgesic and antipyretic acts by elevation of the pain threshold through its action on the hypothalamic heat-regulating center.

Indications:
Lagaflex is indicated as an adjuvant to rest and physical therapy along with other measures in musculoskeletal disorders associated with pain, particularly bursitis, fibrositis, torticolis, fibromyositis, sprains, lumbosacral and sacroiliac arthrosis and acute articular rheumatism.

Contra-Indications:
Lagaflex should not be recommended to patients showing hypersensitivity to any of its ingredients.

Precautions:
Carisoprodol is metabolized in the liver and excreted by the kidney. To avoid its excess accumulation, caution should be exercised in administration to patients with compromised liver or kidney function. If a rare sensitivity reaction occurs, the drug should be stopped.

Warnings:
Idiosyncratic Reactions: On very rare occasions, carisoprodol has shown certain idiosyncratic symptoms appearing within minutes or hours, which include extreme weakness, dizziness, ataxia, temporary loss of vision, agitation, euphoria, confusion, and disorientation. Symptoms usually subside over the course of the next several hours. Supportive and symptomatic therapy, including hospitalization, may be necessary.

Usage in Pregnancy and Lactation: Safe usage of carisoprodol in pregnancy or lactation has not been established. Therefore, use of this drug in pregnancy, in nursing mothers, or in women of childbearing potential requires that the potential benefits of the drug be weighed against the potential hazards of the mother and child.

Carisoprodol is presenting breast milk of lactating mothers at concentrations two to four times that of maternal plasma. This factor should be taken into account when use of the drug is contemplated in breast-feeding patients.

Use in Children: Because of limited clinical experience, carisoprodol is not recommended for use in patients under 12 years of age.

Potentially Hazardous Tasks: Patients should be warned that this drug may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a motor vehicle or operating machinery.

Additive Effects: Since the effects of carisoprodol and alcohol or carisoprodol and other CNS depressants or psychotropic drugs may be additive, appropriate caution should be exercised with patients who take more than one of these agents simultaneously.

Side effects:
Central Nervous System: Drowsiness and other CNS effects may require dosage reduction. Also observed are dizziness, vertigo, ataxia, tremor, agitation, irritability, headache, depressive reactions, syncope, and insomnia.

Cardiovascular: Tachycardia, postural hypotension, and facial flushing.

Gastrointestinal: Nausea, vomiting, hiccup, and epigastric distress.

Hematologic: Leukopenia, in which other drugs or viral infection may have been responsible, and pancytopenia, attributed to phenylbutazone, have been reported. No serious blood dyscrasias have been attributed to carisoprodol.

Drug Interactions:
There is no information available regarding any possible drug interactions.

Overdosage:
Overdosage of carisoprodol may produce coma, shock, respiratory depression, and very rarely, death. The effects of an overdosage of carisoprodol and alcohol or other CNS depressants or psychotropic agents can be additive even when one of the drugs has been taken in the usual recommended dosage.

Treatment:
The stomach should be emptied promptly by lavage or induction of emesis with syrup of ipecac. A serum acetaminophen assay should be obtained at the earliest and liver function studies should be done initially and repeated at 24-hours intervals. The antidote, N-acetylcysteine, should be administered as early as possible.

Dosage:
Adults: 1 to 2 tablets every 6 to 8 hours.
Children: 1/2 to 1 tablet every 8 hours.

Storage:
Store at room temperature (15-25°C) in the original packaging.

Keep out of the reach of children. The preparation is stable up to expiry date (EXP) shown on commercial pack.

Presentation:
Packs of 20's & 1000's Tablets.

This is a Medicament

- Medicament is a product which affects your health, and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instruction 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 medicament out of the reach of children!

Council Of Arab Health Ministers Union of Arab Pharmacists

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