SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

LAGAFLEX Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Carisoprodol 300mg and Paracetamol 250mg.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic 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.

4.2 Posology and method of administration

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

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

4.3 Contraindications

Lagaflex should not be recommended to patients showing hypersensitivity to any of its ingredients.

4.4 Special warnings and precautions for use

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.

Lactose

This medicine contain lactose. Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

There is no information available regarding any possible drug interactions.

4.6 Fertility, 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 in 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

4.7 Effects on ability to drive and use machines

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.

4.8 Undesirable 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.

4.9. Overdose

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.

5. PHARMACOLOGICAL PROPERTIES

Mechanism of action

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.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Povidone, Maize Starch, Lactose, Croscarmellose Sodium, Sodium Lauryl sulphate, Stearic Acid, Magnesium stearate.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

60 Months.

6.4. Special precautions for storage

Store at room temperature (15-25°C) in the original packaging.
Keep out of reach of children. The preparation is stable up to expiry date (EXP) shown on commercial pack.

6.5. Nature and contents of container

Lagaflex Tablets 10's blister packing (using printed aluminium foil on one side and PVDC coated PVC film on other side). are supplied in blister packed in a carton box along with leaflet.

6.6 Special precautions for disposal

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

7. MARKETING AUTHORISATION HOLDER

Lagap SA, UAE
Po. Box 46222
Abu Dhabi, UAE
(A division of Lagap Switzerland)

8. MARKETING AUTHORISATION NUMBER(S)

05266/07289/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of Approval : 11-08-2020