SUMMARY PRODUCT CHARACTERISTICS (SPC):

MONTECOR PLUS(Montelukast and Levocetirizine Dihydrochloride Tablets)

1.1 Strength:

Each uncoated tablet contains:
Montelukast Sodium USP
equivalent to Montelukast : 10 mg
Levocetirizine Dihydrochloride USP: 5 mg

1.2 Pharmaceutical Dosage Form:

Oral Tablets.

2. Qualitative and Quantitative Composition:

Each uncoated tablet contains:
Montelukast Sodium USP
equivalent to Montelukast : 10 mg
Levocetirizine Dihydrochloride USP: 5 mg
Excipients : q.s.
Colour: Yellow Oxide of Iron and Red Oxide of Iron

2.1 Qualitative Declaration:

For Excipients see section 6.1

2.2 Quantitative Declaration:

Montelukast Sodium USP
equivalent to Montelukast : 10 mg
Levocetirizine Dihydrochloride USP: 5 mg
For Excipients see section 6.1

3. Pharmaceutical Form: Oral tablets

Light brown colored, round, flat uncoated tablets having break line mark on one side and plain on the other side.

4. Clinical Particulars

4.1 Therapeutic Indications:

MONTECOR PLUS are indicated for chronic allergic conditions like seasonal allergic rhinitis, perennial allergic rhinitis, rhinitis associated with asthma in adults and adolescents aged 15 years or older.

4.2 Posology and Methods of Administration:

Posology: The recommended dose of montelukast and levocetirizine dihydrochloride Tablet is one tablet once a day.
Method of administration: Oral use.
The dose can be taken with or without food. The tablet should be taken whole. Do not Chew the tablet.
Not recommended for administration in patients below 15 years of age.

4.3 Contraindications:

MONTECOR PLUS is contraindicated in patients with known hypersensitivity to Montelukast Sodium, Levocetirizine or Cetirizine or to any other component of this product. It is also contraindicated in patients with severe renal impairment at less than 10mL/min creatinine clearance.

4.4 Special warning and precautions for use:

Montelukast and levocetirizine dihydrochloride tablets are not treatment for Asthma. Montelukast and levocetirizine dihydrochloride tablets should not be prescribed for the treatment of asthma. However, it may be prescribed with other medications used for the management of asthma.
LEVOCETIRIZINE DIHYDROCHLORIDE: Precaution is recommended with concurrent intake of alcohol. Caution should be taken in patients with predisposing factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as levocetirizine may increase the risk of urinary retention. Caution should be taken in patients with epilepsy and patients at risk of convulsion as levocetirizine may cause seizure aggravation. Response to allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose- galactose malabsorption should not take this medicine. Pruritus may occur when levocetirizine is stopped even if those symptoms were not present before treatment initiation. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

MONTELUKAST: Patients should be advised never to use oral montelukast to treat acute asthma attacks and to keep their usual appropriate rescue medication for this purpose readily available. If an acute attack occurs, a short-acting inhaled beta-agonist should be used. Patients should seek their doctor's advice as soon as possible if they need more inhalations of short-acting

beta-agonists than usual. Montelukast should not be substituted abruptly for inhaled or oral corticosteroids. There is no data demonstrating that oral corticosteroids can be reduced when montelukast is given concomitantly.

Neuropsychiatric events such as behavioural changes, depression and suicidality have been reported in all age groups taking montelukast (see section 4.8). The symptoms may be serious and continue if the treatment is not withdrawn. Therefore, the treatment with montelukast should be discontinued if neuropsychiatric symptoms occur during treatment. Advise patients and/or caregivers to be alert for neuropsychiatric events and instruct them to notify their physician if these changes in behaviour occur.

Treatment with montelukast does not alter the need for patients with aspirin-sensitive asthma to avoid taking aspirin and other non-steroidal anti-inflammatory drugs. This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of Interactions

Montelukast: ln drug-interaction studies, the recommended clinical dose at montelukast did not have clinically important effects on the pharmacokinetics of the following drugs: theophylline, prednisone, prednisolone, oral contraceptives (norethindrone 1 mg/ethinyl estradiol 35 mcg), tertenadine, digoxin, and warfarin. Although additional specific interaction studies were not performed montelukast was used concomitantly with a wide range of commonly prescribed drugs in clinical studies without evidence of clinical adverse interactions. These medications included thyroid hormones, sedative hypnotics, non-steroidal anti-inflammatory agents, benzodiazepines, and decongestants. Phenobarbital, which induces hepatic metabolism, decreased the AUC of montelukast approximately 40% following a single 10-mg dose of montelukast. No dosage adjustment for montelukast is recommended.

Levocetirizine

In vitro data indicates that levocetirizine is unlikely to produce pharmacokinetic interactions through inhibition or induction of liver drug-metabolizing enzymes. No in vivo drug-drug interaction studies have been performed with levocetirizine. Drug interaction studies have been performed with racemic cetirizine. Pharmacokinetic interaction studies performed with racemic cetirizine demonstrated that cetirizine did not interact with antipyrine, pseudoephedrine, erythromycin, glipizide and diazepam, azithromycin, ketoconazole and cimetidine. There was a small decrease (~16%) in the clearance of cetirizine caused by a 400 mg dose of theophylline. It is possible that higher theophylline doses could have a greater effect. Ritonavir increased the plasma AUC of cetirizine by about 42% accompanied by an increase in half-life (53%) and a decrease in clearance (29%) of cetirizine. The disposition of ritonavir was not altered by concomitant cetirizine administration.

Renal Impairment: As Levocetirizine is mainly excreted through urine, dosage adjustment may be required in patients with impaired renal function. Hence this combination should be used with caution in such patients.

Hepatic Impairment: As montelukast is mainly excreted through bile, caution is to be exercise while prescribing this combination in patients with impaired hepatic function.

4.6 Fertility, Pregnancy and Lactation:

Pregnancy: As a precautionary measure, it is preferable to avoid the use of levocetirizine and/or montelukast during pregnancy.
Breast-feeding: A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from levocetirizine / montelukast therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.
Fertility: There are no data available on male and female fertility.

4.7 Effects on ability to drive and use machines.

Some patients could experience somnolence, fatigue and asthenia under therapy with levocetirizine. As there is individual variation in response to all medicinal products, it is recommended that patients are advised not to engage in activities requiring mental alertness, such as driving a car or using machines, until they have established their own response to the medicinal product.

4.8 Side Effects:

Montelukast & Levocetirizine are generally well tolerated. Common side effects, which might be seen with the combination, are dyspepsia, abdominal pain, rash, dizziness, headache, fatigue, and somnolence. Sometimes, hypersensitivity, irritability, restlessness, insomnia, vomiting and diarrhea may occur. In rare cases, patients may present with systemic eosinophilia, sometimes presenting with clinical features of consistent with Churg Strauss Syndrome.
Reporting of suspected adverse reactions: Reporting of suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions to the

4.9 OVERDOSAGE

There is no data reported on the overdosage of this combination. However, overdosage has been reported with individual molecules. Montelukast There have been reports of acute overdosage in post-marketing experience and clinical studies with montelukast. These include reports in adults and children with a dose as high as 1000 mg. The clinical and laboratory findings observed were consistent with the safety profile in adults and pediatric patients. There were no adverse experiences in the majority of overdosage reports. The most frequently occurring adverse experiences were consistent with the safety profile of montelukast and included abdominal pain,

somnolence, thirst, headache, vomiting and psychomotor hyperactivity. It is not known whether montelukast is removed by peritoneal dialysis or hemodialysis.

Levocetirizine

Symptoms of overdose may include drowsiness in adults and initially agitation and restlessness followed by drowsiness in children. There is no known specific antidote to levocetirizine. Should overdose occur, symptomatic or supportive treatment is recommended. Levocetirizine is not effectively removed by dialysis and dialysis will be ineffective unless a dialyzable agent has been concomitantly ingested.

5. Pharmacological Properties:

5.1 Pharmacodynamic Properties:

Pharmacotherapeutic group: Leukotriene receptor antagonist, Antihistamines for systemic use, piperazine derivative

ATC Code:

Montelukast: R03DC03

Levocetirizine: R06AE09

Montelukast: Montelukast causes inhibition of airway cysteinyl leukotriene receptors as demonstrated by the ability to inhibit bronchoconstriction due to inhaled LTD4 in asthmatics. Doses as low as 5 mg cause substantial blockage of LTD4 -induced bronchoconstriction.

Levocetirizine: Levocetirizine, the (R) enantiomer of cetirizine, is a potent and selective antagonist of peripheral H1 receptors.

Binding studies revealed that levocetirizine has high affinity for human H1- receptors (Ki = 3.2 nmol/l). Levocetirizine has an affinity 2-fold higher than that of cetirizine (Ki = 6.3 nmol/l). Levocetirizine dissociates from H1-receptors with a half-life of 115 ±38 min.

Pharmacodynamic studies in healthy volunteers demonstrate that, at half the dose, levocetirizine has comparable activity to cetirizine, both in the skin and in the nose.

Pharmacokinetic/pharmacodynamic relationship 5 mg levocetirizine provide a similar pattern of inhibition of histamine-induced wheal and flare than 10 mg cetirizine. As for cetirizine, the action on histamine-induced skin reactions was out of phase with the plasma concentrations. ECGs did not show relevant effects of levocetirizine on QT interval.

5.2 Pharmacokinetic interactions

Pharmacokinetic Properties

Montelukast:

***Absorption*:** After administration of a 10-mg film-coated tablet to fasted adults, the mean peak montelukast plasma concentration (Cmax) is achieved in 3 to 4 hours (Tmax). The mean oral bioavailability is 64%. The oral bioavailability and Cmax are not influenced by a standard meal in the morning.

***Distribution*:** Montelukast is more than 99% bound to plasma proteins. The steady-state volume of distribution of montelukast averages 8 to 11 liters.
***Metabolism*:** Montelukast is extensively metabolized. In studies with therapeutic doses, plasma concentrations of metabolites of montelukast are undetectable at steady state in adults and pediatric patients.
Elimination: The plasma clearance of montelukast averages 45 mL/min in healthy adults. Following an oral dose of radiolabeled montelukast, 86% of the radioactivity was recovered in 5-day fecal collections and <0.2% was recovered in urine. Coupled with estimates of montelukast oral bioavailability, this indicates that montelukast and its metabolites are excreted almost exclusively via the bile.
In several studies, the mean plasma half- life of montelukast ranged from 2.7 to 5.5 hours in healthy young adults. The pharmacokinetics of montelukast are nearly linear for oral doses up to 50 mg. During once daily dosing with 10-mg montelukast, there is little accumulation of the parent drug in plasma (~14%).

Levocetirizine
The pharmacokinetics of levocetirizine are linear with dose and time-independent with low inter-subject variability. The pharmacokinetic profile is the same when given as the single enantiomer or when given as cetirizine. No chiral inversion occurs during the process of absorption and elimination.
***Absorption*:** Levocetirizine is rapidly and extensively absorbed following oral administration. Peak plasma concentrations are achieved 0.9h after dosing. Steady state is achieved after two days. Peak concentrations are typically 270 ng/ml and 308 ng/ml following a single and a repeated 5 mg o.d. dose, respectively. The extent of absorption is dose-independent and is not altered by food, but the peak concentration is reduced and delayed.
***Distribution*:** No tissue distribution data are available in humans. Levocetirizine is 90% bound to plasma proteins. The distribution of levocetirizine is restrictive, as the volume of distribution is 0.4l/kg.
Biotransformation: The extent of metabolism of levocetirizine in humans is less than 14% of the dose and therefore differences resulting from genetic polymorphism or concomitant intake of enzyme inhibitors are expected to be negligible. Metabolic pathways include aromatic oxidation, N- and O-dealkylation and taurine conjugation. 3 Dealkylation pathways are primarily mediated by CYP 3A4 while aromatic oxidation involved multiple and/or unidentified CYP isoforms. Levocetirizine had no effect on the activities of CYP isoenzymes 1A2, 2C9, 2C19, 2D6, 2E1 and 3A4 at concentrations well above peak concentrations achieved following a 5 mg oral dose. Due to its low metabolism and absence of metabolic inhibition potential, the interaction of levocetirizine with other substances, or vice-versa, is unlikely. The plasma half-life in adults is
7.9 + 1.9 hours. The mean apparent total body clearance is 0.63 ml/min kg. The major route of excretion of levocetirizine and metabolites is via urine, accounting for a mean of 85.4% of the dose. Excretion via feces accounts for only 12.9% of the dose. Levocetirizine is excreted both by glomerular filtration and active tubular secretion.

5.3 Preclinical safety Data:

Non-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

6. Pharmaceutical Particulars:

6.1 List of excipients:

Sr. No.	Ingredients	Specification
1.	Lactose	BP
2.	Microcrystalline Cellulose PH-102	BP
3.	Povidone K-30	USP
4.	Maize Starch (Dried)	BP
5.	Isopropyl Alcohol	BP
6.	Croscarmellose Sodium	USP
7.	Yellow Iron Oxide	IH
8.	Red oxide of Iron	IH
9.	Purified Talc	BP
10.	Magnesium Stearate	BP
11.	Sodium Starch Glycolate	BP

6.2 Incompatibilities: Not known

6.3 Shelf life: 36 Months

6.4 Special precautions for storage:

Store below 30° in dry place. Protect from light. Keep medicine out of reach of children.

Nature and contents of container:

Primary Packing: 10 tablets to be packed in Alu-Alu Blister.

Secondary Packing: Such 1 blisters to be packed in a carton along with pack insert.

6.5 Special Precaution for Disposal and other handling: None

7. Marketing Authorization Holder and Manufacturing Site Address:

Coral Laboratories Limited

#3B, Patanwala Compound, Opp. Shreyas Cinema,
L.B.S. Marg, Ghatkopar (West),
Mumbai – 400 086, INDIA

Manufacturing Site

(Company) Name: CORAL LABORATORIES LIMITED

Company Name: **CORAL LABORATORIES LIMITED**

Address : Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman, India Phone : 91-0260-2263 489, 2263 923
Fax : 91-0260-2263 923
Email : daman@corallab.com.

8. Marketing Authorization Numbers:

CTD13448

9. Date of first Registration /renewal of the Registration:

24/05/2026

10. Date of revision of the text:

24/05/2026