For the use of only a Registered Medical Practitioner or a Hospital or a Laboratory

Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Montelukast Sodium and Levocetirizine Hydrochloride Tablets IP
(Brand Name: SOLITAIR® Tablets)

2. Qualitative and Quantitative Composition

Each film-coated tablet contains:
Montelukast Sodium IP equivalent to Montelukast …… 10 mg.
Levocetirizine Hydrochloride IP ……... … 5 mg.
Excipients …….. q.s.
Colour: Titanium Dioxide IP

3. Dosage Form and Strength

Dosage Form: Tablets.
Dosage Strength: Montelukast 10 mg and levocetirizine hydrochloride 5 mg per tablet.

4. Clinical Particulars

4.1 Therapeutic Indication

SOLITAIR Tablets are indicated for the symptomatic treatment of allergic rhinitis (seasonal and perennial) in adults only.

4.2Posology and Method of Administration

Oral: Adults: 1 tablet to be administered once daily. SOLITAIR Tablets can be administered regardless of food.
Or, as prescribed by the physician.

4.3Contraindications

SOLITAIR Tablets are contraindicated in following conditions:

- Known hypersensitivity to levocetirizine or other piperazine derivatives or to montelukast or to any component of the formulation.
- End stage renal disease (ESRD) patients (creatinine clearance <10 ml/min) and patients undergoing hemodialysis.
- Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

4.4Special Warnings and Precautions for Use

Montelukast

Acute Asthma: Montelukast is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmatics. Patients should be advised to have appropriate rescue medication available. Patients who have exacerbations of asthma after exercise should have a short-acting inhaled β-agonist available as rescue medication.

Concomitant Corticosteroid Use: While the dose of inhaled corticosteroid may be reduced gradually under medical supervision, montelukast should not be abruptly substituted for inhaled or oral corticosteroids.

Aspirin Sensitivity: Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking montelukast. Although montelukast is effective in improving airway function in asthmatics with documented aspirin sensitivity, it has not been shown to truncate bronchoconstrictor response to aspirin and other non-steroidal anti-inflammatory drugs in aspirin-sensitive asthmatic patients.

Hereditary Problems: Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take montelukast.

Eosinophilic Conditions: In rare cases, patients on therapy with anti-asthma agents including montelukast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition which is often treated with systemic corticosteroid therapy. These cases usually, but not always, have been associated with the reduction or withdrawal of oral corticosteroid therapy. The possibility that leukotriene receptor antagonists may be associated with emergence of Churg-Strauss syndrome can neither be excluded nor established. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. Patients who develop these symptoms should be reassessed and their treatment regimens evaluated.

Neuropsychiatric Events: Neuropsychiatric events have been reported in adult, adolescent, and pediatric patients taking montelukast. Post-marketing reports with montelukast use include agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, hallucinations, insomnia, irritability, memory impairment, restlessness, somnambulism, suicidal thinking and behavior (including suicide), and tremor. The clinical details of some post-marketing reports involving montelukast appear consistent with a drug-induced effect. Patients and prescribers should be alert for neuropsychiatric events. Patients should be instructed to notify their prescriber if these changes occur. Prescribers should carefully evaluate the risks and benefits of continuing treatment with montelukast if such events occur.

Levocetirizine

Somnolence: In clinical trials, the occurrence of somnolence, fatigue, and asthenia has been reported in some patients under therapy with levocetirizine. Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness, and motor coordination such as operating machinery or driving a motor vehicle after ingestion of levocetirizine.

Concurrent use of levocetirizine with alcohol or other central nervous system depressants should be avoided because additional reductions in alertness and additional impairment of central nervous system performance may occur.

Urinary Retention: Urinary retention has been reported with levocetirizine. Levocetirizine should be used with caution in patients with predisposing factors of urinary retention (e.g., spinal cord lesion, prostatic hyperplasia) as levocetirizine may increase the risk of urinary retention. Discontinue levocetirizine if urinary retention occurs.

4.5Drug Interactions

Montelukast

Theophylline, prednisone, prednisolone, oral contraceptives (ethinyl estradiol/ norethindrone 35 mcg/1mg), terfenadine, digoxin, and warfarin: The recommended clinical dose of montelukast did not have clinically important effects on the pharmacokinetics of these drugs.

CYP 450 inducers such as phenytoin, phenobarbital, and rifampicin: The area under the plasma concentration curve (AUC) for montelukast was decreased approximately 40% in subjects with co-administration of phenobarbital. Since montelukast is metabolised by CYP 3A4, 2C8, and 2C9, caution should be exercised, particularly in children, when montelukast is co-administered with inducers of CYP 3A4, 2C8, and 2C9, such as phenytoin, phenobarbital and rifampicin.

Paclitaxel, rosiglitazone, and repaglinide: *In vitro* studies have shown that montelukast is a potent inhibitor of CYP 2C8. However, data from a clinical drug-drug interaction study involving montelukast and rosiglitazone (a probe substrate representative of medicinal products primarily metabolized by CYP 2C8) demonstrated that montelukast does not inhibit CYP 2C8 *in vivo*. Therefore, montelukast is not anticipated to markedly alter the metabolism of medicinal products metabolised by this enzyme (e.g., paclitaxel, rosiglitazone, and repaglinide).

Gemfibrozil: *In vitro* studies have shown that montelukast is a substrate of CYP 2C8, and to a less significant extent of 2C9, and 3A4. In a clinical drug-drug interaction study involving montelukast and gemfibrozil (an inhibitor of both CYP 2C8 and 2C9) gemfibrozil increased the systemic exposure of montelukast by 4.4-fold. No routine dosage adjustment of montelukast is required upon co-administration with gemfibrozil or other potent inhibitors of CYP 2C8, but the physician should be aware of the potential for an increase in adverse reactions.

Trimethoprim: Based on *in vitro* data, clinically important drug interactions with less potent inhibitors of CYP 2C8 (e.g., trimethoprim) are not anticipated.

Itraconazole: Co-administration of montelukast with itraconazole, a strong inhibitor of CYP 3A4, resulted in no significant increase in the systemic exposure of montelukast.

Levocetirizine

In vitro data indicate 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.

Antipyrine, azithromycin, cimetidine, erythromycin, ketoconazole, theophylline, and pseudoephedrine: Pharmacokinetic interaction studies performed with racemic cetirizine

demonstrated that cetirizine did not interact with antipyrine, pseudoephedrine, erythromycin, 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: 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.

4.6Use in Special Populations

Pregnant Women

Montelukast: Pregnancy Category B; Levocetirizine: Pregnancy Category B.

Animal studies with individual agents do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development. However, there are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this product should be used during pregnancy only if clearly needed.

Lactating Women

Studies in rats have shown that montelukast is excreted in milk. It is not known if montelukast is excreted in human milk. Cetirizine has been reported to be excreted in human breast milk. Levocetirizine is also expected to be excreted in human milk. Thus, use of this product in nursing mothers is not recommended.

Paediatric Patients

This product is not indicated for use in children due to its higher dosage strength. However, if use of these medicines is necessary in children, pediatric formulations of desired dosage strength can be used appropriately.

Geriatric Patients

Usually, no dose adjustment is considered necessary in elderly patients with normal renal function. Elderly patients are more likely to have decreased renal function. Levocetirizine is mainly excreted by the kidneys and thus, risk of adverse reactions might be greater in this population. Care should be taken while dose selection and it may be useful to monitor renal function.

Renal Impairment Patients

Montelukast is negligibly excreted by urine. Levocetirizine is known to be substantially excreted by the kidneys and the risk of adverse reactions may be greater in patients with impaired renal function. Thus, dose adjustment is recommended in patients with moderate to severe renal impairment. Also, use of this product is contraindicated in patients with End-Stage Renal Disease (ESRD) and patients undergoing hemodialysis.

Hepatic Impairment Patients

As levocetirizine is mainly excreted unchanged by the kidneys, it is unlikely that the clearance of levocetirizine is significantly decreased in patients with hepatic dysfunction. With montelukast, no dosage adjustment is required in patients with mild-to-moderate hepatic insufficiency. Thus, SOLITAIR Tablets can be administered in patients with mild-to-moderate hepatic impairment.

4.7Effect on Ability to Drive and Use Machines

Dizziness may occur in some individual with levocetirizine. Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness, and motor coordination such as operating machinery or driving a motor vehicle after ingestion of this product.

4.8Undesirable Effects

Montelukast

Clinical Trials Experience

The most common adverse reactions (incidence ≥ 5% and greater than placebo) in controlled clinical trials were upper respiratory infection, fever, headache, pharyngitis, cough, abdominal pain, diarrhea, otitis media, influenza, rhinorrhea, and sinusitis.

Adverse experiences occurring in ≥ 1% of patients with an incidence greater than that in patients treated with placebo were:

- Body as a whole: Asthenia/fatigue, fever, trauma.
- Digestive system disorders: Dyspepsia, pain (abdominal), gastroenteritis (infectious).
- Nervous system/psychiatric: Headache, dizziness.
- Respiratory system disorders: Influenza, cough, congestion (nasal).
- Skin/skin appendages disorder: Rash.
- Abnormal laboratory tests: Increase in ALT, increase in AST, pyuria.

Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of montelukast. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Blood and lymphatic system disorders: Increased bleeding tendency, thrombocytopenia.
- Immune system disorders: Hypersensitivity reactions including anaphylaxis, hepatic eosinophilic infiltration.
- Psychiatric disorders: Agitation including aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, hallucinations, insomnia, irritability, memory impairment, restlessness, somnambulism, suicidal thinking and behavior (including suicide), and tremor.
- Nervous system disorders: Drowsiness, paraesthesia/hypoesthesia, seizures.
- Cardiac disorders: Palpitations.
- Respiratory, thoracic and mediastinal disorders: Epistaxis, pulmonary eosinophilia.

- Gastrointestinal disorders: Diarrhea, dyspepsia, nausea, pancreatitis, vomiting.
- Hepatobiliary disorders: Cases of cholestatic hepatitis, hepatocellular liver-injury, and mixed-pattern liver injury have been reported in patients treated with montelukast. Most of these occurred in combination with other confounding factors, such as use of other medications, or when montelukast was administered to patients who had underlying potential for liver disease such as alcohol use or other forms of hepatitis.
- Skin and subcutaneous tissue disorders: Angioedema, bruising, erythema multiforme, erythema nodosum, pruritus, Stevens-Johnson syndrome/toxic epidermal necrolysis, urticaria.
- Musculoskeletal and connective tissue disorders: Arthralgia, myalgia including muscle cramps.
- General disorders and administration site conditions: Edema.

Levocetirizine

Clinical Trials Experience

Common adverse reactions reported with levocetirizine in clinical trials were somnolence, fatigue, asthenia (physical weakness), dry mouth, headache, abdominal pain, nasopharyngitis/pharyngitis, and urinary retention. Most of these side effects were mild to moderate in intensity.

Post-Marketing Experience

In addition to the adverse reactions reported during clinical studies and listed above, very rare cases of the following adverse drug reactions have been reported in post-marketing experience.

- Immune system disorders: Hypersensitivity, including anaphylaxis.
- Psychiatric disorders: Aggression, agitation.
- Nervous system disorders: Convulsions.
- Eye disorders: Visual disturbances.
- Cardiac disorders: Palpitations.
- Respiratory, thoracic, and mediastinal disorders: Dyspnea.
- Gastrointestinal disorders: Nausea.
- Hepatobiliary disorders: Hepatitis.
- Skin and subcutaneous tissue disorders: Angioneurotic oedema, fixed drug eruptions, pruritus, rash, urticaria.
- Musculoskeletal, connective tissue, and bone disorders: Myalgia.
- Investigations: Increased weight, abnormal liver function tests.

4.9Overdose

There are no published reports on overdose of this combination product. However, overdose has been reported with individual components of this product as follows:

Montelukast

Symptoms: There have been reports of acute overdose 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 overdose 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.

Treatment: No specific information is available on the treatment of overdose with montelukast. Should overdose occur, symptomatic or supportive treatment is recommended. It is not known whether montelukast is dialysable by peritoneal or haemodialysis.

Levocetirizine

Symptoms: Symptoms of overdose may include drowsiness in adults and initially agitation and restlessness, followed by drowsiness in children.

Treatment: There is no known specific antidote to levocetirizine. Should overdose occur, symptomatic or supportive treatment is recommended. Gastric lavage should be considered following short-term ingestion. Levocetirizine is not effectively removed by haemodialysis.

5. Pharmacological Properties

5.1 Mechanism of Action

Montelukast

The cysteinyl leukotrienes (LTC_4, LTD_4, LTE_4) are products of arachidonic acid metabolism and are released from various cells, including mast cells and eosinophils. These eicosanoids bind to cysteinyl leukotriene (CysLT) receptors. The CysLT type-1 ($CysLT_1$) receptor is found in the human airway (including airway smooth muscle cells and airway macrophages) and on other pro-inflammatory cells (including eosinophils and certain myeloid stem cells).

CysLTs have been correlated with the pathophysiology of asthma and allergic rhinitis. In asthma, leukotriene-mediated effects include airway edema, smooth muscle contraction, and altered cellular activity associated with the inflammatory process. In allergic rhinitis, CysLTs are released from the nasal mucosa after allergen exposure during both early-and late-phase reactions and are associated with symptoms of allergic rhinitis.

Montelukast is an orally active compound that binds with high affinity and selectivity to the $CysLT_1$ receptor (in preference to other pharmacologically important airway receptors, such as the prostanoid, cholinergic, or β-adrenergic receptor). Montelukast inhibits the physiologic actions of LTD_4 at the $CysLT_1$ receptor without any agonist activity.

Levocetirizine

Levocetirizine, the active enantiomer of cetirizine, is an anti-histaminic agent. Its principal effects are mediated via selective inhibition of H_1 receptors. The antihistaminic activity of levocetirizine has been documented in a variety of animal and human models. *In vitro* binding studies revealed that levocetirizine has an affinity for the human H_1 receptor 2-fold higher than that of cetirizine.

5.2Pharmacodynamic Properties

Montelukast

The cysteinyl leukotrienes (LTC_4, LTD_4, LTE_4) are released from various cells, including airway smooth muscle cells, mast cells, and eosinophils. The cysteinyl leukotrienes (CysLTs) are involved in the pathophysiology of asthma and allergic rhinitis. Montelukast is an oral leukotriene receptor ($CysLT_1$) antagonist useful in the management of asthma and allergic rhinitis.

Levocetirizine

Levocetirizine is a non-sedating, selective histamine H_1 receptor antagonist, with antihistamine and anti-inflammatory properties. Levocetirizine competes with endogenous histamine for binding at peripheral H_1-receptor sites on the effector cell surface and treat a variety of allergic symptoms including allergic rhinitis.

5.3Pharmacokinetic Properties

Montelukast

Absorption: Montelukast is rapidly absorbed following oral administration. After administration of the 10 mg film-coated tablet to fasted adults, the mean peak montelukast plasma concentration (C_{max}) is achieved in 3 to 4 hours (T_{max}). The mean oral bioavailability is 64%. The oral bioavailability and C_{max} 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. Studies in rats with radiolabeled montelukast indicate minimal distribution across the blood-brain barrier. In addition, concentrations of radiolabeled material at 24 hours post-dose were minimal in all other tissues.

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.

In vitro studies using human liver microsomes indicate that CYP3A4, 2C8, and 2C9 are involved in the metabolism of montelukast. At clinically relevant concentrations, 2C8 appears to play a major role in the metabolism of montelukast.

Excretion: 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 is 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

Levocetirizine exhibited linear pharmacokinetics over the therapeutic dose range in adult healthy subjects.

Absorption: Levocetirizine is rapidly and extensively absorbed following oral administration. In adults, peak plasma concentrations are achieved 0.9 hour after administration of the oral tablet. The accumulation ratio following daily oral administration is 1.12 with steady state achieved after 2 days. Peak concentrations are typically 270 ng/ml and 308 ng/ml following a single and a repeated 5 mg once daily dose, respectively. Food had no effect on the extent of exposure (AUC) of the levocetirizine tablet, but T_{max} was delayed by about 1.25 hours and C_{max} was decreased by about 36% after administration with a high fat meal; therefore, levocetirizine can be administered with or without food.

Distribution: The mean plasma protein binding of levocetirizine *in vitro* ranged from 91 to 92%, independent of concentration, in the range of 90 to 5000 ng/ml, which includes the therapeutic plasma levels observed. Following oral dosing, the average apparent volume of distribution is approximately 0.4 l/kg, representative of distribution in total body water.

Metabolism: The extent of metabolism of levocetirizine in humans is less than 14% of the dose. Therefore, differences resulting from genetic polymorphism or concomitant intake of hepatic drug metabolizing enzyme inhibitors are expected to be negligible.

Metabolic pathways include aromatic oxidation, N-and O-dealkylation, and taurine conjugation. Dealkylation pathways are primarily mediated by CYP 3A4 while aromatic oxidation involves multiple and/or unidentified CYP isoforms.

Excretion: The plasma half-life in adult healthy subjects was about 8 to 9 hours after administration of oral tablets and oral solution, and the mean oral total body clearance for levocetirizine was approximately 0.63 ml/kg/min. The major route of excretion of levocetirizine and its 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. Renal clearance of levocetirizine correlates with that of creatinine clearance. In patients with renal impairment the clearance of levocetirizine is reduced.

6. Nonclinical Properties

6.1 Animal Toxicology

Montelukast

Carcinogenicity: No evidence of tumorigenicity was seen in carcinogenicity studies of either 2 years in Sprague-Dawley rats or 92 weeks in mice at oral gavage doses up to 200 mg/kg/day or 100 mg/kg/day, respectively. The estimated exposure in rats was approximately 120 and 75 times the AUC for adults and children, respectively, at the maximum recommended daily oral dose. The estimated exposure in mice was approximately 45 and 25 times the AUC for adults and children, respectively, at the maximum recommended daily oral dose.

Mutagenesis: Montelukast demonstrated no evidence of mutagenic or clastogenic activity in the following assays: the microbial mutagenesis assay, the V-79 mammalian cell mutagenesis assay, the alkaline elution assay in rat hepatocytes, the chromosomal aberration assay in Chinese hamster ovary cells, and in the in vivo mouse bone marrow chromosomal aberration assay.

Impairment of Fertility: In fertility studies in female rats, montelukast produced reductions in fertility and fecundity indices at an oral dose of 200 mg/kg (estimated exposure was approximately 70 times the AUC for adults at the maximum recommended daily oral dose). No effects on female fertility or fecundity were observed at an oral dose of 100 mg/kg (estimated exposure was approximately 20 times the AUC for adults at the maximum recommended daily oral dose). Montelukast had no effects on fertility in male rats at oral doses up to 800 mg/kg (estimated exposure was approximately 160 times the AUC for adults at the maximum recommended daily oral dose).
Teratogenicity: In embryo-fetal development studies, montelukast administered to pregnant rats and rabbits during organogenesis (gestation days 6 to 17 in rats and 6 to 18 in rabbits) did not cause any adverse developmental effects at maternal oral doses up to 400 and 300 mg/kg/day in rats and rabbits, respectively (approximately 100 and 110 times the AUC in humans at the maximum recommended human daily oral dose [MRHDOD], respectively).

Levocetirizine

Carcinogenesis: No carcinogenicity studies have been performed with levocetirizine. However, evaluation of cetirizine carcinogenicity studies is relevant for determination of the carcinogenic potential of levocetirizine. In a 2-year carcinogenicity study, in rats, cetirizine was not carcinogenic at dietary doses up to 20 mg/kg (approximately 40, 40, 25, and 10 times the maximum recommended human doses [MRHD] in adults, children 6 to 11 years of age, children 2-5 years, and children 6 months to 2 years of age, respectively, on a mg/m2 basis). In a 2-year carcinogenicity study in mice, cetirizine caused an increased incidence of benign hepatic tumors in males at a dietary dose of 16 mg/kg (approximately 15, 15, 9, and 5 times the MRHDs in adults, children 6 to 11 years of age, children 2-5 years, and children 6 months to 2 years of age, respectively, on a mg/m2 basis). No increased incidence of benign tumors was observed at a dietary dose of 4 mg/kg (approximately 4, 4, 2, and 1 times the MRHDs in adults, children 6 to 11 years of age, children 2-5 years, and children 6 months to 2 years of age, respectively on a mg/m2 basis). The clinical significance of these findings during long-term use of levocetirizine is not known.
Mutagenesis: Levocetirizine was not mutagenic in the Ames test, and not clastogenic in the human lymphocyte assay, the mouse lymphoma assay, and *in vivo* micronucleus test in mice.
Impairment of Fertility: Fertility and reproductive performance were unaffected in male and female mice and rats that received cetirizine at oral doses up to 64 and 200 mg/kg/day, respectively (approximately 60 and 390 times the MRHD in adults on a mg/m2 basis).
Teratogenicity: In embryo-fetal development studies, pregnant rats received daily doses of levocetirizine up to 200 mg/kg/day from gestation days 6 to 15 and pregnant rabbits received daily doses of levocetirizine up to 120 mg/kg/day from gestation days 6 to 18. Levocetirizine produced no evidence of fetal harm in rats and rabbits at doses up to 390 and 470 times the MRHD, respectively (on a mg/m2 basis with maternal oral doses of 200 and 120 mg/kg/day in rats and rabbits, respectively).

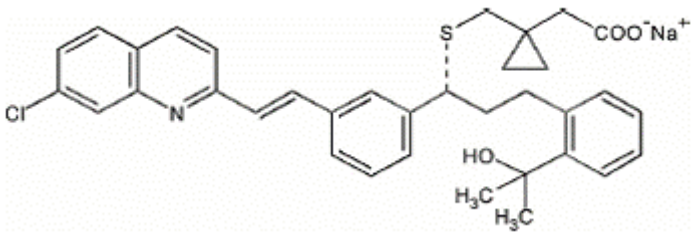
7. Description

SOLITAIR Tablets are White coloured, round, biconvex, plain on both sides & film coated tablets.

Each tablet of SOLITAIR contains 10 mg of montelukast and 5 mg of levocetirizine for oral administration in adults.

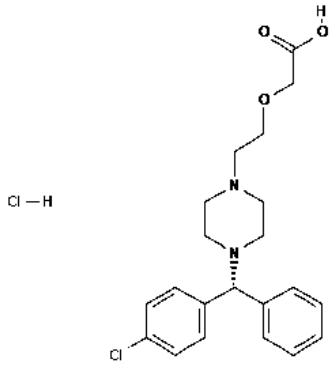
Montelukast Sodium

Montelukast sodium, the sodium salt of montelukast, is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene $CysLT_1$ receptor.
Montelukast sodium is a hygroscopic, optically active, white to off-white powder.
Molecular Weight: 608.18 g/mol.
Chemical Name: [R-(E)]-1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]thio]methyl]cyclopropaneacetic acid, monosodium salt.
Molecular Formula: C35H35ClNNaO3S.
Structural Formula:



Levocetirizine Hydrochloride

Levocetirizine hydrochloride is an orally active H_1-receptor antagonist. Levocetirizine is the R enantiomer of cetirizine, a racemic compound with antihistaminic properties.
Levocetirizine hydrochloride appears as a white, crystalline powder.
Molecular Weight: 425.3 g/mol.
Chemical Name: 2-[2-[4-[(R)-(4-chlorophenyl)-phenylmethyl]piperazin-1-yl]ethoxy]acetic acid;hydrochloride.
Molecular Formula: C21H26Cl2N2O3.
Structural Formula:



Inactive ingredients : Starch, Lactose, Sodium Bi-Carbonate, Polyvinyl Pyrrolidone, Purified Water, Magnesium Stearate, Talcum, Colloidal Silicon Dioxide, Crospovidone, Hydroxy Propyl Methyl Cellulose, Polyethylene Glycol, Titanium Dioxide, Isopropyl Alcohol & Methylene Chloride.

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2Shelf-life

24 Months

8.3Packaging Information

Strip of 10 tablets.

8.4Storage and Handling Instructions

Store protected from light and moisture, at a temperature not exceeding 30°C.
Keep out of reach of children.

9. Patient Counseling Information

Instructions to Patients

- Do not take SOLITAIR Tablets if you are allergic to any of its ingredients.
- Take SOLITAIR exactly as prescribed by your doctor. Do not exceed the dose (because of the increased risk of drowsiness at higher doses) or duration of treatment.
- Stop taking SOLITAIR Tablets and consult your doctor immediately if you have any unusual changes in behavior or thinking. Serious mental health problems have been reported in people taking montelukast or even after treatment have stopped.
- Pregnant women and breastfeeding mothers to consult with their doctor before use of this medicine.
- This medicine should be strictly avoided in patients with end-stage renal disease (ESRD) and patients undergoing hemodialysis.
- SOLITAIR Tablets can be taken with or without food.
- Levocetirizine may cause sedation/dizziness in some individuals. If affected, patients are advised not to operate machinery or drive a motor vehicle after ingestion of this medicine.
- Instruct patients to avoid concurrent use of this medicine (as it contains levocetirizine) with alcohol or other central nervous system (CNS) depressants because additional reduction in mental alertness may occur.

10. Details of Manufacturer

Akums Drugs & Pharmaceuticals Ltd.

Plot No. 26A, 27, 28, 29 & 30, Sector – 8A, I.I.E., Sidcul, Haridwar 249403.

11. Details of Permission or License Number with Date

Mfg. Lic. No. : 4/UA/LL/2014, Date of FDA Product Permission: 23/01/2018

12. Date of Revision

March 2021.

Marketed by:

BLUE CROSS LABORATORIES PVT LTD.

A-12, M.I.D.C., NASHIK-422 010.

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