Summary Product Characteristics

1. Name of the medicinal product

MONTIZINE Syrup (Montelukast Sodium BP and Levocetirizine Dihydrochloride USP syrup)

2. Qualitative and quantitative composition

Each 5 ml Contains:
Levocetirizine Dihydrochloride USP ……2.5 mg
Montelukast Sodium BP Eq. to Montelukast….4 mg
Flavored Syrup Base.……..Q.S.

3. Pharmaceutical form

Clear Colorless flavored base syrup.

4. Clinical particulars

4.1 Therapeutic indications

Indicated for Chronic Allergic conditions like seasonal allergic rhinitis, perennial allergic rhinitis, Rhinitis associated with Asthma.

4.2 Posology and method of administration

Posology
For oral administration
Dosage
Children 2 to 5 years of age: 5ml once a day
Children below 2 of age as per physician instruction

4.3 Contraindications

Patients with a known hypersensitivity to Levocetirizine Dihydrochloride or Montelukast sodium, or to any of the excipients, to hydroxyzine or to any piperazine derivatives.
Patients with severe renal impairment at less than 10 ml/min creatinine clearance.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.
Levocetirizine Dihydrochloride is not recommended in children
Do not consume alcohol while taking Montelukast and Levocetirizine may cause additional reductions in alertness and impairment of performance
Caution in epileptic patients and patients at risk of convulsions are recommended.
Montelukast and Levocetirizine is contraindicated in patients with an allergy to either or both drugs, hepatic impairment, NSAID allergy, Churg-Strauss syndrome

4.5 Interaction with other medicinal products and other forms of interaction

Montelukast sodium:
In drug-interaction studies, the recommended clinical dose of Montelukast sodium 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), terfenadine, digoxin, and warfarin.
Although additional specific interaction studies were not performed, Montelukast sodium 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 sodium approximately 40% following a single 10-mg dose of Montelukast sodium.
No dosage adjustment for Montelukast sodium is recommended. It is reasonable to employ appropriate clinical monitoring when potent cytochrome P450 enzyme inducers, such as phenobarbital or rifampin, are co-administered with Montelukast sodium
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.

In sensitive patients the simultaneous administration of cetirizine or Levocetirizine Dihydrochloride and alcohol or other CNS depressants may have effects on the central nervous system, although it has been shown that the racemate cetirizine does not potentiate the effect of alcohol.

Renal Impairment

Levocetirizine Dihydrochloride is known to be substantially excreted by the kidneys and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. 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 Levocetirizine Dihydrochloride is mainly excreted unchanged by the kidneys, it is unlikely that the clearance of Levocetirizine Dihydrochloride is significantly decreased in patients with solely hepatic impairment. But Montelukast sodium is mainly excreted through bile; caution is to be exercised while prescribing this combination in patients with impaired hepatic function.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate and well controlled studies of either Montelukast sodium, or Levocetirizine Dihydrochloride in pregnant women. Because animal reproduction studies are not always predictive of human response, this combination should not be used during pregnancy only if it is considered to be clearly essential.

Lactation:

It is not known if Montelukast sodium is excreted in human milk. Cetirizine has
been reported to be excreted in human breast milk. Because Levocetirizine
Dihydrochloride is also expected to be excreted in human milk this combination is not recommended during lactation.

4.7 Effects on ability to drive and use machines

Administration is occasionally associated with drowsiness and somnolence, Patients should make sure that they are not affected before driving or using machinery

4.8 Undesirable effects

Generally well tolerated. *Common in side effects,* Which might be seen with the combination, are diarrhoea, nausea, vomiting ,dyspepsia; abdominal pain, elevated levels of serum transaminases (ALT, AST,rash, dizziness, headache, pyrexia, fatigue and somnolence.

Rare cases, Increased bleeding tendency, disturbance in attention, memory impairment, palpitations, angioedema ,Hepatic eosinophilic infiltration, hallucinations, disorientation, suicidal thinking and behaviour (suicidality), Churg-Strauss Syndrome (CSS), hepatitis (including cholestatic, hepatocellular, and mixed-patternliver injury), erythema nodosum, erythema multiform

Uncommon cases, Hypersensitivity reactions including anaphylaxis, Dizziness, drowsiness, paraesthesia/ hypoesthesia, insomnia, somnambulism, anxiety, agitation, depression, irritability, restlessness, tremor,
epistaxis, Dry mouth, bruising, urticaria, pruritus, arthralgia, myalgia including muscle cramps,
asthenia/fatigue, malaise, oedema.

4.9 Overdose

Symptoms observed after an overdose of Levocetirizine are mainly associated with CNS effects or with effects that could suggest an anticholinergic effect.

Adverse events reported after an intake of at least 5 times the recommended daily dose are: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor and urinary retention.

Management of overdoses

There is no known specific antidote to Levocetirizine.

Should overdose occur, symptomatic or supportive treatment is recommended.

Gastric lavage should be considered following ingestion of a short occurrence. Levocetirizine/Montelukast is not effectively removed by dialysis.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Combination of Antihistamine and leukotriene receptor antagonist
Levocetirizine Dihydrochloride. Antihistamine for systemic use, piperazine derivatives,
ATC Code: R06A E09
Montelukast sodium: leukotriene receptor antagonist ATC-code: R03DC53.
Montelukast sodium -antileukotriene anti-asthmatics, for systemic use)., is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene ($CysLT_1$)receptor. Montelukast inhibits bronchoconstriction due to inhaled LTD4 at doses as low as 5 mg. Bronchodilation was observed within 2 hours of oral administration Levocetirizine Dihydrochloride. -Antihistamines for systemic use - Piperazine derivatives. 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. After single administration, levocetirizine shows a receptor occupancy of 90% at 4 hours and 57% at 24 hours. 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 provides a similar pattern of inhibitionof histamine-induced wheal and flare as 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 properties

Levocetirizine Dihydrochloride.

Absorption:

Levocetirizine is rapidly and extensively absorbed following oral administration. Peak plasma concentrations are achieved 0.9 h 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, neither concerning the passage of Levocetirizine through the blood-brain-barrier. Levocetirizine is 90% bound to plasma proteins.

The distribution of Levocetirizine is restrictive, as the volume of distribution is 0.4 l/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. 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.

Elimination: 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 meanof 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 impairment : The apparent body clearance of Levocetirizine is correlated to the creatinine clearance. It is therefore recommended to adjust the dosing intervals of Levocetirizine, based on creatinine clearance inpatients with moderate and severe renal impairment. In anuric end stage renal disease subjects, the total body clearance is decreased by approximately 80% when compared to normal subjects.

Montelukast sodium

Absorption : Montelukast is rapidly absorbed following oral administration. For the 10 mg film-coated tablet, the mean peak plasma concentration (Cmax) is achieved 3 hours (Tmax) after administration in adults in thefasted state. The mean oral bioavailability is 64%. The oral bioavailability and Cmax are not influenced by a standard meal. Safety and efficacy were demonstrated in clinical trials where the 10 mg film-coated tablet was administered without regard to the timing of food ingestion.

Biotransformation : Montelukast is extensively metabolised. In studies with therapeutic doses, plasma concentrations of metabolites of Montelukast are undetectable at steady state in adults and children.

Cytochrome P450 2C8 is the major enzyme in the metabolism of Montelukast. Additionally CYP 3A4 and 2C9 may have a minor contribution, although itraconazole, an inhibitor of CYP 3A4, was shown not to change pharmacokinetic variables of Montelukast in healthy subjects that received 10 mg Montelukast daily. Based on in vitro results in human liver microsomes, therapeutic plasma concentrations of Montelukast do not inhibit cytochromes P450 3A4, 2C9, 1A2, 2A6, 2C19, or 2D6. The contribution of metabolites to the therapeutic effect of Montelukast is minimal.

Elimination: The plasma clearance of Montelukast averages 45 ml/min in healthy adults. Following an oral dose of radiolabelled Montelukast, 86% of the radioactivity was recovered in 5-day faecal 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.

Characteristics in patients

No dosage adjustment is necessary for the elderly or mild to moderate hepatic insufficiency. Studies in patients with renal impairment have not been undertaken. Because Montelukast and its metabolites are eliminated by the biliary route, no dose adjustment is anticipated to be necessary in patients with renal impairment. There are no data on the pharmacokinetics of Montelukast in patients with severe hepatic insufficiency (Child-Pugh score>9).With high doses of Montelukast (20- and 60-fold the recommended adult dose), decrease in plasma theophylline concentration was observed. This effect was not seen at the recommended dose of 10 mg once daily.

5.3 Preclinical safety data

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

6. Pharmaceutical particulars

6.1 List of excipients

Glycerin
Sodium Methyl Paraben
Sodium Propyl Paraben
Sucralose
Acrysol K - 150
Poly Ethylene Glycol 400
Di Sodium EDTA
Flavour Rose white
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30°C.Protected from direct sunlight
Keep all medicines out of reach of children.

6.5 Nature and contents of container
60ml Amber coloured PET bottle, packed in a unit boxes, with literature insert.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7.0Manufactured by:
Company Name: NEURON PHARMA PVT. LTD.
Address: Plot No. PF-15, Opp. P & G Pharma, Sanand GIDC - II. Sanand,
Dist. Ahmedabad -382110.
Country: INDIA
Telephone: +91 9825217597
Web site: www.neuronpharma.com

8.0 Marketing authorisation holder
Company Name: NEURON PHARMA PVT. LTD.
Address: Plot No.PF-15, Opp. P & G Pharma, Sanand GIDC - II. Sanand,
Dist. Ahmedabad - 382110.
Country: INDIA
Telephone: +91 9825217597
Web site: www.neuronpharma.com

9.0 Legal category:
Prescription only medicine, (POM)

10. Date of revision of the text
April 2022

KM00014A

Montizine Syrup

100 mm

Levocetirizine Dihydrochloride & Montelukast Sodium Syrup

Montizine Syrup

60 ml

Neuron
(WHO GMP CERTIFIED CO)

42 mm

Montizine Syrup

Each 5 ml contains :

Levocetirizine Dihydrochloride USP	2.5 mg
Montelukast Sodium BP Eq. to Montelukast	4 mg
In Flavoured Syrup base	Q.S.

Not recommended for children below 6 months.

Dosage: As per directed by the physician.

Storage : Store below 30° C temperature. Protect from light and moisture.

Keep the medicine out of reach of children.

FOR PAEDIATRIC USE ONLY.

SHAKE WELL BEFORE USE.

To be sold under prescription of a medical practitioner

42 mm

Levocetirizine Dihydrochloride & Montelukast Sodium Syrup

Montizine Syrup

60 ml

Neuron
(WHO GMP CERTIFIED CO)

Montizine Syrup

Mfg. Lic. No.:GUJ/DRUGS/G/25/2373
Batch No.:
Mfg. Date :
Exp. Date :

Manufactured in India by:

Neuron Pharma Pvt. Ltd.

Plot No. PF-15, Opp. P&G Pharma, Sanand GIDC-II, Sanand-382110. Ahmedabad. Gujarat. INDIA.
www.neuronpharma.com

Imported & Distributed in Kenya by:

FOURMEDS PHARMACEUTICALS LTD
P.O. Box 516623-00100, Nairobi, Kenya.
info@fourmedspharma.co.ke
www.fourmedspharma.co.ke

90 mm

45 mm

Each 5 ml contains :
Levocetirizine Dihydrochloride USP 2.5 mg
Montelukast Sodium BP
Eq. to Montelukast 4 mg
In Flavoured Syrup base Q.S.

Not recommended for children below 6 months.

Dosage: As per directed by the physician.

Storage : Store below 30° C temperature. Protect from light and moisture.

Keep the medicine out of reach of children.

FOR PAEDIATRIC USE ONLY.

SHAKE WELL BEFORE USE.

KL0001A

To be sold under prescription of a medical practitioner

Levocetirizine Dihydrochloride & Montelukast Sodium Syrup

Montizine
Syrup

60 ml

Neuron

Mfg. Lic. No.:GUJ/DRUGS/G/25/2373
Batch No.:
Mfg. Date :
Exp. Date :

Manufactured in India by:

Neuron Pharma Pvt. Ltd.

Plot No. PF-15, Opp. P&G Pharma, Sanand GIDC-II, Sanand-382110. Ahmedabad. Gujarat. INDIA.
www.neuronpharma.com

Imported & Distributed in Kenya by:

FOURMEDS PHARMACEUTICALS LTD
P.O. Box 516623-00100, Nairobi, Kenya.
info@fourmedspharma.co.ke
www.fourmedspharma.co.ke

Montizine Syrup
(Levocetirizine Dihydrochloride And Montelukast Sodium Syrup)

Composition
Each 5 ml Contains:
Levocetirizine Dihydrochloride USP……2.5mg
Montelukast Sodium USP Eq. Montelukast…….4mg
Excipients: ..... q.s.

Pharmaceutical form
Clear Colorless flavored base syrup.
Pharmacodynamic properties
Pharmacotherapeutic group: Combination of Antihistamine and leukotriene receptor antagonist
Levocetirizine Dihydrochloride. Antihistamine for systemic use, piperazine derivatives, ATC Code: R06A E09
Montelukast sodium: leukotriene receptor antagonist ATC-code: R03DC53.
Montelukast sodium -antileukotriene anti-asthmatics, for systemic use)., is a selective and orally active
leukotriene receptor antagonist that inhibits the cysteinyl leukotriene (CysLT1)receptor. Montelukast inhibits
bronchoconstriction due to inhaled LTD4 at doses as low as 5 mg. Bronchodilation was observed within 2 hours of oral administration Levocetirizine Dihydrochloride.-Antihistamines for systemic
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(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. After single administration, Levocetirizine shows a receptor occupancy of 90% at 4 hours and 57% at 24 hours
Pharmacokinetics
Absorption: After administration of the 10-mg tablet 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.
Metabolism: Montelukast is extensively metabolized. In studies with therapeutic doses, Plasma concentrations of metabolites of Montelukast are undetectable at steady state in pediatric patients.
Elimination: The plasma clearance of Montelukast averages 45 ML/min. 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.
The pharmacokinetics of Montelukast are nearly linear for oral doses UP to 50 mg.
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 0.9gh after dosing. Steady state is achieved after two days.
Peak concentrations are typically 270ng/ml and 308ng/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 i s restrictive, as the volume of distribution is 0.41/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. 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 iso-enzymes 1A2, 2C9, 2C19, 206, 2E1 and 3A4 at concentrations well above peak concentrations achieved following 5mg 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 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 faeces accounts for only 12.9% of the dose. Levocetirizine is excreted both by glomerular filtration and active tubular secretion
Indications
indicated for the relief of symptoms of allergic rhinitis
Seasonal or perennial, as prophylaxis in seasonal allergic rhinitis and treatment of comorbid asthma and allergic rhinitis in patients 2 to 5 years of age.
Dosage and administration:
For oral administration
To be taken orally.
Dosage
Children 2 to 5 years of age: 5ml once a day
Children below 2 of age as per physician instruction
Undesirable effects.
Generally well tolerated. Common in side effects, Which might be seen with the combination, are diarrhoea, nausea, vomiting ,dyspepsia; abdominal pain, elevated levels of serum transaminases (ALT, AST,rash, dizziness, headache, pyrexia, fatigue and somnolence. Rare cases, Increased bleeding tendency, disturbance in attention, memory impairment, palpitations, angioedema ,Hepatic eosinophilic infiltration, hallucinations, disorientation, suicidal thinking and behaviour (suicidality), Churg-Strauss Syndrome (CSS), hepatitis (including cholestatic, hepatocellular, and mixed-pattern liver injury), erythema nodosum, erythema multiform Uncommon cases, Hypersensitivity reactions including anaphylaxis, Dizziness, drowsiness, paraesthesia/ hypoesthesia, insomnia, somnambulism, anxiety, agitation, depression, irritability, restlessness, tremor, epistaxis, Dry mouth, bruising, urticaria, pruritus, arthralgia, myalgia including muscle cramps, asthenia/fatigue, malaise, oedema..
Warnings/precautions
Montelukast is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus. Patients should be advised to have appropriate rescue medication available. Therapy with Montelukast can be continued during acute exacerbations of asthma. While the dose of inhaled corticosteroid may be reduced gradually under medical supervision, Montelukast should not be abruptly substituted for inhaled or oral corticosteroids.
Montelukast should not be used as monotherapy for the treatment and management of exercise -induced bronchospasm. Patients who have exacerbations of asthma after exercise should continue to use their usual regimen of inhaled (beta)-agonists as prophylaxis and have available for rescue a short-acting inhaled (beta)-agonist.
Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking Eosinophilia Conditions: In rare cases, patients on therapy with 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 events usually, but not always, have been associated with the reduction of oral corticosteroid therapy.
Levocetirizine: Precaution is recommended with intake of alcohol.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose•galactose malabsorption should not take this medicine.

Drug interactions
Interaction with other medicinal products and other forms of interaction
Due to the pharmacokinetic, pharmacodynamic and tolerance profile of levocetirizine, no interactions are expected with this antihistamine.
Montelukast + Levocetirizine may interact with phenytoin, CNS depressants, rifampicin, prednisone and phenobarbital.
Do not consume alcohol while taking Montelukast + Levocetirizine
Plasma concentration curve (AUC) for Montelukast IS decreased approximately 40% in subjects with co-administration of phenobarbital.
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, prednisone phenobarbital and rifampicin.

Pregnancy and lactation
Pregnancy: There are no adequate and well-controlled studies of either Montelukast or Levocetirizine in pregnant women. Hence this combination should not be used during pregnancy.
Lactation: Caution should be exercised when prescribing to pregnant or breast feeding women because Levocetirizine passes into breast milk.
Effects on ability to drive and use machines:
Administration is occasionally associated with drowsiness and somnolence, Patients should make sure that they are not affected before driving or using machinery
Overdose and treatment
There is no data to prove the over dosage of this combination. However, over-dosage has been reported with individual molecules.
Montelukast: 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 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
Shelf life:
3 years from the date of manufacture
Presentation:
60ml syrup in amber coloured bottle in unit box with literature insert included
Storage:
Store in a dry place at a temperature below 30°C. Keep all medicines out of reach of children.
Legal category:
Prescription only medicine, (POM).
Manufactured By:
NEURON PHARMA PVT. LTD.
Plot No. PF-15, Opp. P & G Pharma, Sanand GIDC - II. Sanand,
Dist. Ahmedabad -382110. India
Web site: www.neuronpharma.com