CARIDINE SYRUP 0.5mg/ml

DESCRIPTION
CARIDINE SYRUP is a clear orange, fruity flavoured syrup.

COMPOSITION
Each 1 ml of **CARIDINE SYRUP** contains 0.5 mg of desloratadine.
Preservative: Sodium benzoate 1mg/ml

PHARMACODYNAMICS
Pharmacotherapeutic group: antihistamines – H_1 antagonist, ATC code: R06A X27

Mechanism of action
Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H_1-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H_1-receptors because the substance does not readily penetrate the central nervous system.

Desloratadine has demonstrated antiallergic, antihistaminic, and anti-inflammatory activity.

Since histamine release is a causal factor in all urticarial diseases, desloratadine is expected to be effective in providing symptomatic relief for other urticarial conditions, in addition to chronic idiopathic urticaria.

Desloratadine inhibits the broad cascade of events that initiate and propagate allergic inflammation, including: -

- release of proinflammatory cytokines including IL-4, IL-6, IL-8, IL-13,
- release of important proinflammatory chemokines such as RANTES (Regulated upon Activation, Normal T-cell Expressed and Secreted),
- superoxide anion production by activated polymorphonuclear neutrophils,
- eosinophil adhesion and chemotaxis,
- the expression of the adhesion molecules such as P-selectin,
- IgE-dependent release of histamine, prostaglandin (PGD2), and leukotriene (LTC4),
- acute allergic bronchoconstrictor response and allergic cough

In addition to the established classifications of seasonal and perennial, allergic rhinitis can alternatively be classified as intermittent allergic rhinitis and persistent allergic rhinitis according to the duration of symptoms. Intermittent allergic rhinitis is defined as the presence of symptoms for less than 4 days per week or for less than 4 weeks. Persistent allergic rhinitis is defined as the presence of symptoms for 4 days or more per week and for more than 4 weeks.

PHARMACOKINETICS

Absorption
Desloratadine plasma concentrations can be detected within 30 minutes of desloratadine administration in adults and adolescents. Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours; the terminal phase half-life is approximately 27 hours. The degree of accumulation of desloratadine was consistent with its half-life (approximately 27 hours) and a once daily dosing frequency. The bioavailability of desloratadine was dose proportional over the range of 5 mg to 20 mg.

Distribution
Desloratadine is moderately bound (83 % - 87 %) to plasma proteins. There is no evidence of clinically relevant active substance accumulation following once daily adult and adolescent dosing of desloratadine (5 mg to 20 mg) for 14 days.

Biotransformation
The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore, some interactions with other medicinal products cannot be fully excluded. Desloratadine does not inhibit CYP3A4 in vivo, and in vitro studies have shown that the medicinal product does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

INDICATION(S)
CARIDINE SYRUP is indicated for the rapid relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge and itching, congestion/stuffiness, as well as ocular itching, tearing and redness.
CARIDINE SYRUP is also indicated for the relief of symptoms associated with urticaria such as the relief of itching and the size and number of hives.

RECOMMENDED DOSAGE
The prescriber should be aware that most cases of rhinitis below 2 years of age are of infectious origin and there are no data supporting the treatment of infectious rhinitis with **CARIDINE SYRUP.**

Relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticaria: -
Children 1 - 5 years: 2.5 ml (1.25 mg) **CARIDINE SYRUP** once a day, with or without a meal.
Children 6 - 11 years: 5 ml (2.5 mg) **CARIDINE SYRUP** once a day, with or without a meal.
Adult and adolescents (12 years and above): 10 ml (5 mg) **CARIDINE SYRUP** once a day, with or without a meal.

Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or for less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance.

In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks), continued treatment may be proposed to the patients during the allergen exposure periods.

ROUTE OF ADMINISTRATION: Oral

CONTRAINDICATIONS
Hypersensitivity to the active substance or to any of the excipients, or to loratadine.

WARNINGS AND PRECAUTIONS
Convulsions
Desloratadine should be administered with caution in patients with medical or familial history of seizures, and mainly young children, being more susceptible to develop new seizures under desloratadine treatment. Discontinuation of desloratadine may be considered in patients who experience a seizure while on treatment.

Paediatric population: In children below 2 years of age, the diagnosis of allergic rhinitis is particularly difficult to distinguish from other forms of rhinitis. The absence of upper respiratory tract infection or structural abnormalities, as well as patient history, physical examinations, and appropriate laboratory and skin tests should be considered. Approximately 6% of adults and children 2- to 11-years old are poor metabolisers of desloratadine and exhibit a higher exposure. The safety of desloratadine in children 2- to 11-years of age who are poor metabolisers is the same as in children who are normal metabolisers. The effects of desloratadine in poor metabolisers <2 years of age have not been studied.

The safety and efficacy of **CARIDINE SYRUP** in children below the age of 1 year have not been established.

In the case of severe renal insufficiency, **CARIDINE SYRUP** should be used with caution.

INTERACTIONS WITH OTHERS MEDICAMENTS
No clinically relevant interactions with desloratadine tablets were observed where erythromycin or ketoconazole were co-administered.
There was no effect of food or grapefruit juice on the disposition of desloratadine.
CARIDINE SYRUP taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol. However, cases of alcohol intolerance and intoxication have been reported. Therefore, caution is recommended if alcohol is taken concomitantly.

USE IN PREGNANCY AND LACTATION
Use in Pregnancy: No teratogenic or mutagenic effects were observed in animal trials with desloratadine. However, no clinical data on exposed pregnancies are available with desloratadine, hence the safe use of **CARIDINE SYRUP** during pregnancy has not been established. **CARIDINE SYRUP** is to be avoided during pregnancy unless the potential benefits outweigh the risks.
Use in Lactation: Desloratadine is excreted into breast milk, therefore the use of **CARIDINE SYRUP** is not recommended in breast-feeding women.

SIDE EFFECTS/ADVERSE REACTIONS
The most frequent adverse events reported were fatigue, dry mouth and headache. In infants and toddlers aged 6 to 23 months, the most frequent adverse reactions reported were diarrhoea, fever and insomnia. Very rare cases of hypersensitivity reactions, including anaphylaxis and rash have been reported. In addition, cases of tachycardia, palpitations, psychomotor hyperactivity, somnolence, seizures, elevations of liver enzymes, hepatitis and increased bilirubin have been reported very rarely.

Paediatric population
Other undesirable effects reported in paediatric patients with unknown frequency includes QT prolongation, arrhythmia, bradycardia, abnormal behaviour and aggression.

Size: 29cm(H) x 15cm(W)

Black 100%

Tabulated list of adverse reactions

System Organ Class	Frequency	Adverse reactions seen with Desloratadine
Metabolism and nutrition disorders	Not known	Increased appetite
Psychiatric disorders	Very rare	Hallucinations
	Not known	Abnormal behaviour, aggression
Nervous system disorders	Common	Headache
	Common (children less than 2 years)	Insomnia
	Very rare	Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures
Cardiac disorders	Very rare	Tachycardia, palpitations
	Not known	QT prolongation
Gastrointestinal disorders	Common	Dry mouth
	Common (children less than 2 years)	Diarrhoea
	Very rare	Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea
Hepatobiliary disorders	Very rare	Elevations of liver enzymes, increased bilirubin, hepatitis
	Not known	Jaundice
Skin and subcutaneous tissue disorders	Not known	Photosensitivity
Musculoskeletal and connective tissue disorders	Very rare	Myalgia
General disorders and administration site conditions	Common	Fatigue
	Common (children less than 2 years)	Fever
	Very rare	Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria)
	Not known	Asthenia
Investigations	Not known	Weight increased

SYMPTOMS AND TREATMENT OF OVERDOSE
In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatments are recommended. Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.
No clinically relevant effects were observed in adults and adolescents when up to 45 mg of desloratadine was administered (nine times the clinical dose).

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
No effects or negligible influence on the ability to drive and use machines have been observed. Most people do not experience drowsiness. Nevertheless, 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.

STORAGE CONDITIONS
Store below 30°C. Store in original container.
Protect from light. Shake well before use.
Keep out of reach of children. *Jauhkan daripada kanak-kanak.*

PACKING/ PACK SIZES
Supplied in amber PET bottle of 60ml with measuring cup.

SHELF LIFE
Please refer to outer product label.

PRODUCT REGISTRATION HOLDER
Duopharma Marketing Sdn. Bhd.
Lot No.2, 4, 6, 8 & 10, Jalan P/7, Section 13,
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