DESTAVELL 5MG Film Coated Tablet

CONTENT
Each Destavell contains 5.0 mg of desloratadine.

DESCRIPTION
Blue film-coated tablet, round, convex, plain on one side and breakline on the other.

PHARMACODYNAMICS
Pharmacotherapeutic group: antihistamines.

H1 antagonist, ATC code: R06AX27

Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H1-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H1- receptors because the substance is excluded from entry to the central nervous system.

Desloratadine has demonstrated antiallergic properties including inhibit the release of proinflammatory cytokines such as IL-4, IL-6, IL-8, and IL-13 from human mast cells/basophils, as well as inhibition of the expression of the adhesion molecule P-selectin on endothelial cells.

Desloratadine does not readily penetrate the central nervous system. At the recommended dose of 5 mg daily, there was no excess incidence of somnolence as compared to placebo. Desloratadine given at a single daily dose of 7.5 mg did not affect psychomotor performance. Desloratadine 5 mg did not affect standard measures of flight performance including exacerbation of subjective sleepiness or tasks related to flying.

In patients with allergic rhinitis (AR), Destavell was effective in relieving symptoms such as sneezing, nasal discharge and itching, as well as ocular itching, tearing and redness, and itching of palate. Destavell effectively controlled symptoms for 24 hours. Efficacy has not been clearly demonstrated in patients 12.17 years of age.

Destavell was effective in relieving pruritus and decreasing the size and number of hives by the end of the first dosing interval. The effects were sustained over the 24-hour dosing interval. Treatment with Destavell also significantly reduced interference with sleep and daytime function, as measured by a four-point scale used to assess these variables.

Destavell was effective in alleviating the burden of seasonal allergic rhinitis (SAR) as shown by the total score of the rhino-conjunctivitis quality of life questionnaire. The greatest amelioration was seen in the domains of practical problems and daily activities limited by symptoms.

PHARMACOKINETICS
Desloratadine plasma concentrations can be detected within 30 minutes of administration. 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.

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

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

There was no effect of food (high-fat, high caloric breakfast) and grapefruit juice on the disposition of desloratadine.

INDICATION
Destavell 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.

Destavell are also indicated for the relief of symptoms associated with chronic idiopathic urticaria such as the relief of itching and the size and number of hives.

RECOMMENDED DOSAGE
Adults and adolescents (12 years of age and over): one tablet once a day, with or without a meal.

For oral use.

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

WARNING AND PRECAUTIONS
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. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment.

INTERACTION OF OTHER MEDICAMENTS
No clinically relevant interactions with Destavell were observed. There was no effect of food or grapefruit juice on the disposition of desloratadine.

Destavell taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol (see Pharmacodynamics).

PREGNANCY AND LACTATION
Pregnancy

As a precautionary measure, it is preferable to avoid the use of desloratadine during pregnancy.

Breast-feeding

Desloratadine has been identified in breastfed newborns/infants of treated women. The effect of desloratadine on newborns/infants is unknown. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from desloratadine 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.

RANCANGAN LEAFLET DESTAVELL TABLET EKSPOR MALAYSIA

Specification :

Material : HVS 60 gsm
Dimension : Length : 170 mm
Width : 150 mm
Design :
- Product name : Black
- Other Text : Black

Character :
- Product name : ZapfHumnst Dm BT (9 pt)
- Other Text : ZapfHumnst BT (7 pt)

Print Out 100%

SIDE EFFECTS

The most common adverse events are fatigue, dry mouth and headache.

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
	Very rare	Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures
Cardiac disorders	Very Rare	Tachycardia, palpitations
	Not known	QT prolongation
Gastrointestinal disorders	Common	Dry mouth
	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
	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

The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

Treatment

In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended.

Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

Symptoms

No clinically relevant effects were observed.

Paediatric population

The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

Desloratadine has no or negligible influence on the ability to drive and use machines. Most people do not experience drowsiness. Nevertheless, as there is individual variation in response to all medicinal products, it is recommended that 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 CONDITION

Store below 30°C.

Keep medicine out of reach of children.

Protect from excessive moisture. Store in the original container.

Jauhi daripada kanak-kanak!

PACKAGING:

Destavell is packaged in boxes of 3 strips @ 10 film-coated tablets.

MANUFACTURER

PT. Novell Pharmaceutical Laboratories
Jl. Wanaherang, No. 35 Tlajung Udik,
Gunung Putri Bogor, 16962 Indonesia

REVISION DATE: 7 December 2021

Code of Packaging