

Selcet Tablet

(Levocetirizine Dihydrochloride)

سلیسیت ٹیبلٹ
(لیووسٹیریزین ڈائی ہائیڈروکلورائیڈ)

COMPOSITION:

Each film coated tablet contains:

Levocetirizine Dihydrochloride.....5 mg

(USP Specification)

DESCRIPTION:

Selcet tablet is the levo-isomer of cetirizine (levocetirizine) with twice the affinity for H1 receptors, and rapid and long-lasting antihistaminic action, as compared with cetirizine.

INDICATIONS:

Selcet tablet is recommended in patients 6 years and above for the treatment of allergic conditions like allergic rhinitis (seasonal as well as perennial), allergic conjunctivitis and chronic idiopathic urticaria.

MODE OF ACTION:

Selcet tablet is a potent, selective, peripheral H-1 receptor antagonist with negligible effects on other receptors.

DOSE & ADMINISTRATION:

In adults and children older than 6 years:

The recommended daily dose of Selcet tablet is 5mg.

In children of age 6 -12 years: 5 mg tablet should be given in two divided doses.

In children aged 2 to 6 years:

The recommended daily dose of Selcet tablet is 2.5mg in children of age 2-6 years, in two divided doses.

In patients with renal impairment:

The dose of Selcet tablet in renal dysfunction should be titrated as follows i.e. according to creatinine clearance of the patient:

Creatinine Clearance (ml/min)	Selcet Tablet Dose
50 - >80	1 tablet daily
30 - 49	1 tablet every 2nd day
10 - 29	1 tablet every third day
<10	not recommended

PHARMACOKINETICS:

- The time required for Selcet tablet to reach peak plasma levels (t_{max}) is approx. 1hour.
- Selcet tablet achieve steady-state plasma level by the second day.
- Volume of distribution of Selcet tablet is 0.4 l/kg. Selcet tablet has not been found to penetrate into the brain.
- Selcet tablet is extensively bound to blood components, approx. 7% is the free fraction (which is constant) and the fraction bound to blood cells and plasma proteins is approx. 28% and 66%, respectively.
- Selcet tablet is poorly metabolized (14% of the total oral dose).
- After oral administration to healthy individuals, radioactive Selcet tablets are recovered in urine and faeces, 85% and 13% respectively.
- Of the oral dose, approx. 80% of Selcet tablet is eliminated unchanged in urine in 48 hours.
- Though intake of Selcet tablet with food does not hamper extent of drug absorption, it's speed of absorption might decrease.

CONTRAINDICATIONS:

- Known, hypersensitivity to the active ingredient or any of the inactive ingredients or to medicines that contain piperazine derivatives. If hypersensitivity, reaction occurs, the patients should stop treatment and immediately report to the physician
- Glucose-galactose malabsorption
- Lactase deficiency
- Hereditary galactose intolerance
- Severe renal impairment

SIDE EFFECTS:

Treatment with Selcet tablet might cause the following temporary side effects:

- Tiredness
- Lack of concentration
- Somnolence
- Headache
- Agitation
- Dry mouth
- Constipation
- Hypersensitivity reactions e.g. Photosensitivity
- Reactions, liver damage, deafness, pruritus, vasculitis etc.
- 95% of the side effects are mild to moderate.

WARNINGS:

- Care should be taken while driving or operating machinery, it is better to avoid these activities during treatment with Selcet tablet since it may cause sedation. The patient should involve in such activities only when he knows that Selcet tablet do not cause sedation in him.
- Drinking excessive amounts of alcohol should be avoided during therapy with Selcet tablet.

PRECAUTIONS:

- Use during Pregnancy:** Safety of Selcet tablet has not been treated in pregnant women.

Though animal studies did not exhibit direct or indirect toxicity during pregnancy, in terms of any effect on fetus, Selcet tablets should be used during pregnancy after doing risk-benefit analysis.

Use during Breast feeding:

Since Selcet tablet is excreted into the milk, Selcet tablet should be prescribed during breast feeding after doing the risk-benefit analysis.

Use in Children:

Use of Selcet tablet has not been evaluated in children < 6 years of-age.

OVERDOSING:

Over dosage with Selcet tablet can cause somnolence. In such cases symptomatic / supportive measures should be undertaken.

DRUG INTERACTIONS:

No drug interaction studies have been conducted with Selcet tablet. Since studies with the cetirizine show no drug interactions with ketoconazole, azithromycin, diazepam, pseudoephedrine, cimetidine, erythromycin and glipizide, it can be deduced that Selcet tablet also do not have interactions with these drugs.

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight & moisture. Keep away from the reach of children. **To be sold on the prescription of a registered medical practitioner only.**

HOW SUPPLIED:

Selcet 5mg Tablet

10's, 20's Tablets.

خوراک و طریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو 15-25 ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:

PHARMASOL
PRIVATE LIMITED
Plot # 549, Sundar Industrial Estate,
Lahore-Pakistan.