**ALAGREN ®**  
(Formic acid 5-amino-2-hydroxy-benzyl ester)

**DESCRIPTION**  
ALAGREN (benzyl N-hydroxycarbamate) inhibits allergic reactions to the peanut allergen *ara h 1*, a major allergen belonging to the vicillin family of seed storage proteins.

\[
\text{OH} \quad \text{NH}_2 \quad \text{O} \\
\text{C}_8\text{H}_9\text{N}_0_3
\]

**Inactive ingredients:**  
Magnesium stearate, mannitol, starch.

**Dosage:**  
ALAGREN is supplied in 20 mg, 30 mg, and 40 mg tablets for oral administration such that 10 mg per liter is distributed in the blood.

**CLINICAL PHARMACOLOGY**  

**Mechanism of Action:**  
Sufficiently binds to peanut allergen, inhibiting the fragmenting of protein *ara h 1*, thereby stopping a systemic allergic reaction.

**Pharmacokinetics:**  
**Absorption:**  
Absorption after an oral dose is relatively rapid (t\(_{\text{max}}\) ~1 hour) and occurs throughout the upper gastrointestinal tract. The fraction of the dose absorbed is independent of dose over the range studied (single dose, 20 to 30 mg). Steady-state conditions in the serum are observed within 57 days of daily dosing. Mean absolute oral bioavailability of the 30 mg tablet is 0.63% (90% CI; 0.54% to 0.75%) and is comparable to a solution. The extent of absorption of a 30 mg dose when administered 0.5 hours before breakfast is reduced by 55% compared to dosing in the fasting state (no food or drink for 10 hours prior to or 4 hours after dosing). Dosing 1 hour prior to breakfast reduces the extent of absorption by 30% compared to dosing in the fasting state. Dosing either 0.5 hours prior to breakfast or 2 hours after dinner (evening meal) results in a similar extent of absorption. ALAGREN is effective when administered at least 30 minutes before breakfast.

**Elimination:**  
Approximately half of the absorbed dose is excreted in urine within 24 hours and 85% is recovered in the urine over 28 days. Mean renal clearance is 105 mL/min 9cv = 34%) and mean total clearance is 122 mL/min (CV = 19%), with the difference primarily reflecting nonrenal clearance. The renal clearance is not concentration dependent, and there is a linear relationship between renal clearance and creatinine clearance. Unabsorbed drug is eliminated unchanged in feces. Once absorbed, the serum concentration-time profile is multi-phasic, with an initial half-life of about 1.5 hours and a terminal exponential half-life of 480 hours.

**Special Populations:**  

**Pediatric:**  
Pharmacokinetics have not been studied in patients <18 years of age.

**Gender:**  
Bioavailability and pharmacokinetics following oral administration are similar in men and women.

**Geriatric:**  
Bioavailability and disposition are similar in elderly (>60 years of age) and younger subjects. No dosage adjustment is necessary.

**Race:**  
Pharmacokinetic differences due to race have not been studied.