# הודעה על החמרה (מידע בטיחות) בעלון לצרכן

**תאריך 07.2011**

**שם תכשיר באנגלית:**

**Kaletra 200 mg/50 mg Tablets**

**Kaletra 100 mg/25 mg Tablets**

**Kaletra Oral solution**

**מספר רישום** 137 96 31542 00, 137 96 31542 01, 141 07 32003 00,

122 05 30210 00

**שם בעל הרישום:** Abbott Laboratories, Israel

השינויים בעלון מסומנים ברקע צהוב

## עלון לצרכן

| פרטים על השינוי/ים המבוקש/ים | | |
|---|---|---|
| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **אין להשתמש בתכשיר מבלי להיוועץ ברופא...** | | אין ליטול תרופה זו אם הינך מטופל/ת בו זמנית עם: סלמטרול (לאסטמה), אלפוזוציל (לטיפול בתסמינים הקשורים להגדלה שפירה של הערמונית), סלדנפריל (לטיפול באין-אונות), חומצה פוסידית (אנטיביוטיקה). |
| **תגובות בין תרופתיות** | | תרופות לטיפול בגאוט (כגון: כולכיצין) |

## עלון לרופא

| פרטים על השינוי/ים המבוקש/ים | | |
|---|---|---|
| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **DOSAGE AND ADMINISTRATION** | | ***2.2 Pediatric Patients***<br>KALETRA oral solution contains 42.4% (v/v) alcohol and 15.3% (w/v) propylene glycol. Special attention should be given to accurate calculation of the dose of KALETRA, transcription of the medication order, dispensing information and dosing instructions to minimize the risk for medication errors, and overdose. This is especially important for |

infants and young children. Total amounts of alcohol and propylene glycol from all medicines that are to be given to pediatric patients 14 days to 6 months of age should be taken into account in order to avoid toxicity from these excipients *[see Warnings ndPrecautions (5.2) and Overdosage (10)]*.

**Table 3. Drugs That Are Contraindicated With KALETRA**

| Drug Class | Drugs Within Class That Are Contraindicated With KALETRA | Clinical comments: |
|---|---|---|
| Alpha 1-Adrenoreceptor antagonist | Alfuzosin | Potentially increased alfuzosin concentrations can result in hypotension. |
| Antibiotics | Fucidic acid | |
| Antimycobacterial | Rifampin | May lead to loss of virologic response and possible resistance to KALETRA or to the class of protease inhibitors or other co-administered antiretroviral agents. *[see DRUG INTERACTIONS (7)]* |
| Ergot Derivatives | Dihydroergotamine, ergonovine, ergotamine, methylergonovine | Potential for acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues. |
| GI motility agent | Cisapride | Potential for cardiac arrhythmias. |
| Herbal Products | St Johns wort (hypericum perforatum) | May lead to loss of virologic response and possible resistance to KALETRA or to the class of protease inhibitors. |
| HMG-CoA Reductase Inhibitors | Lovastatin, simvastatin | Potential for myopathy including rhabdomyolysis. |
| PDE5 enzyme inhibitor | Sildenafil[a] when used for the treatment of pulmonary arterial hypertension | A safe and effective dose has not been established when used with KALETRA. There is an increased potential for sildenafil-associated adverse events, including visual abnormalities, hypotension, prolonged erection, and syncope *[see Drug Interactions (7)]*. |
| Neuroleptic | Pimozide | Potential for cardiac arrhythmias. |
| Sedative/Hypnotics | orally administered Midazolam[b]; triazolam | Prolonged or increased sedation or respiratory depression. |

**CONTRAINDICATIONS**

| | | |
|---|---|---|
| **5.1 Drug Interactions**- CYP3A Enzyme Inhibition<br>KALETRA is a CYP3A inhibitor. Initiating treatment with KALETRA in patients receiving medications metabolized by CYP3A or initiating medications metabolized by CYP3A in patients already maintained on KALETRA may result in increased plasma concentrations of concomitant medications. Higher plasma concentrations of concomitant medications can result in increased or prolonged therapeutic or adverse effects, potentially leading to severe, life-threatening or fatal events. The potential for drug-drug interactions must be considered prior to and during therapy with KALETRA. Review of other medications taken by patients and monitoring of patients for adverse effects is recommended during therapy with KALETRA.<br><br>**5.2 Toxicity in Preterm Neonates -** KALETRA oral solution contains the excipients alcohol (42.4% v/v) and propylene glycol (15.3% w/v). When administered concomitantly with propylene glycol, ethanol competitively inhibits the metabolism of propylene glycol, which may lead to elevated concentrations. Preterm neonates may be at increased risk of propylene glycol-associated adverse events due to diminished ability to metabolize propylene glycol, thereby leading to accumulation and potential adverse events. Postmarketing life-threatening cases of cardiac toxicity (including complete AV block, bradycardia, and cardiomyopathy), lactic acidosis, acute renal failure, CNS depression and respiratory complications leading to death have been reported, predominantly in preterm neonates receiving KALETRA oral solution.<br><br>KALETRA oral solution should not be used in preterm neonates in the immediate postnatal period because of possible toxicities. A safe and effective dose of KALETRA oral solution in this patient | | **Warnings and Precautions** |

| | | |
|---|---|---|
| population has not been established. However, if the benefit of using KALETRA oral solution to treat HIV infection in infants immediately after birth outweighs the potential risks, infants should be monitored closely for increases in serum osmolality and serum creatinine, and for toxicity related to KALETRA oral solution including: hyperosmolality, with or without lactic acidosis, renal toxicity, CNS depression (including stupor, coma, and apnea), seizures, hypotonia, cardiac arrhythmias and ECG changes, and hemolysis. Total amounts of alcohol and propylene glycol from all medicines that are to be given to infants should be taken into account in order to avoid toxicity from these excipients [see *Dosage and Administration (2.2) and Overdosage (10)*].<br><br>**5.4 Hepatotoxicity -** Elevated transaminases with or without elevated bilirubin levels have been reported in HIV-1 mono-infected and uninfected patients as early as 7 days after the initiation of KALETRA in conjunction with other antiretroviral agents. In some cases, the hepatic dysfunction was serious; however, a definitive causal relationship with KALETRA therapy has not been established. | | |
| **6.3 Postmarketing Experience** - *Skin and Appendages*<br>Toxic epidermal necrolysis (TEN), | | **ADVERSE REACTIONS** |
| Anti-gout: colchicines,<br>Contraceptive: ethinyl estradiol* | | **DRUG INTERACTIONS** |
| The following events have been reported in association with unintended overdoses in preterm neonates: complete AV block, cardiomyopathy, lactic acidosis, and acute renal failure *[see Warnings and Precautions (5.2)]*. | | **OVERDOSAGE** |