

Drug errors involving Keppra and Kaletra

The Food & Drug Administration would like to alert healthcare providers that dispensing errors between Keppra (levetiracetam) and Kaletra (lopinavir/ritonavir) have occurred. The FDA has received four reports of confusion between Keppra and Kaletra, one of which resulted in administra-

cally, Keppra and Kaletra are used to treat different conditions, and Kaletra contains two active ingredients while Keppra contains a single active ingredient. Although there is no overlap of the dosage strengths, both products are available in oral solid dosage forms, oral solutions, and are administered twice daily.

and as an oral solution containing 100 mg/ml, and is manufactured by UCB Pharma. The initial dose of Keppra is 500 mg taken twice daily. The dose may be increased at two-week intervals in increments of 1 gm per day, up to a maximum of 3 gm per day. Keppra tablets were approved by the

Postmarketing reports of medication errors for Keppra and Kaletra Intended Unintended Type of				
Date of event	product	product	error	Summary of event
2-01	Keppra	Kaletra	Potential	Although Keppra is not approved for pediatric patients, it is sometimes used for kids who do not respond to currently approved medications. This could increase the risk of errors with Kaletra, which is approved for use in pediatric patients.
1-01	Keppra	Kaletra	Actual	A physician's drug information question concerning Keppra was misinterpreted by the pharmacist as Kaletra, potentially resulting in a wrong recommendation being made. Although the drug name was clarified, this report states that the wrong medication was given to the patient.
1-02	Keppra	Kaletra	Actual	A patient was ordered Keppra 500 mg every 12 hours, but Kaletra was dispensed. Patient was discharged and never received the medication.
1-02	Keppra	Kaletra	Actual	A prescription was correctly processed; however, the wrong drug was pulled from stock, resulting in a bottle of Kaletra being labeled as Keppra. The error was detected prior to the patient taking the medication.

tion of the wrong drug product. Fortunately, this patient did not experience any adverse events as a result of the errors. Two cases were caught prior to patient administration, and the remaining case describes the potential for confusion between the two products due to their sound-alike properties. See table above for a description of the four cases.

Medication errors have occurred despite characteristics that differ between Keppra and Kaletra. SpecifiKeppra contains the active ingredient levetiracetam and is indicated as adjunctive treatment of partial-onset seizures in adults with epilepsy. Keppra is available as 250-, 500-, and 750-mg tablets

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FDA in November 1999, and Keppra oral solution was approved in July 2003.

Kaletra contains a combination of lopinavir and ritonavir and is indicated for treatment of human immunodeficiency virus (HIV) infection. Kaletra is available as an oral capsule in a strength of 133.3 mg/33.3 mg and as an oral solution containing 80 mg/20 mg per milliliter. Kaletra can be taken by adults and by children six months of age and older. The usual adult

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dose of Kaletra is three capsules (400 mg/100 mg) or 5 ml twice daily taken with food. Kaletra oral capsules and oral solution were approved by the FDA in September 2000. The sponsor is Abbott Laboratories.

Based upon the reports received, errors occurred between Keppra and Kaletra due to their sound-alike proprietary names. Keppra and Kaletra are both available in solid oral dosage forms (capsules or tablets) and as an oral solution. Additionally, both products share an overlapping dosing quantity (5 ml) and are administered twice daily. From our perspective, the similarities between the names in addition to the similarities in route of administration, dosage form, and dosing quantity may further increase the risk of confusion between Keppra and Kaletra, particularly if healthcare providers are not educated concerning this potential for confusion.

Clearly, patients with epilepsy or HIV who mistakenly receive an incorrect medication are at risk for experiencing severe health consequences. In addition to not receiving the appropriate lifesaving medication, patients would be at risk for experiencing side effects associated with the unintended drug product.

In order to avert future medication errors between Keppra and Kaletra we recommend:

- Educating healthcare staff (physicians, pharmacists, nurses, nurse practitioners, and technicians) about the potential medication errors between Keppra and Kaletra
- Verifying all orders for Keppra and Kaletra between pharmacists and prescribers by spelling both the proprietary name as well as the established name (e.g., Keppra, levetiracetam)
- •Counseling all patients receiving either Keppra or Kaletra regarding the drug indication, strength, and dosing regimen
- •Including the indications with the prescription when ordering either medication
- •Implementing computerized alerts when prescriptions are processed for Keppra and Kaletra, as well as pharmacy shelf reminders to double-check product selection

Note: Always store Kaletra capsules and oral solution in the refrigerator. This will ensure the two products are not colocated on pharmacy shelves.

If you become aware of prescription dispensing errors involving Keppra and Kaletra, please contact the FDA MedWatch program by telephone at 1-(800) FDA-1088, by fax at 1-(800) FDA-0178, or by Internet at www.fda.gov/medwatch.

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