

OCTOBER

2004

**FORMULARY PRODUCT TRANSITION:
LILLY BRAND INSULIN (HUMULIN)
TO
NOVO NORDISK BRAND INSULIN (NOVOLIN)
UPDATE**

Additional changes have been to the KU Hospital Formulary regarding the change of Humulin brand insulin products to Novolin products. This product switch will decrease expenses for the institution and more accurately reflect our outpatient market share. The following table has been revised to reflect the insulin products that will be affected by this change in the formulary.

Humulin N, R and 70/30 will be included in a brand switch to Novolin products. A therapeutic automatic substitution policy will replace Humalog (insulin lispro) with Novolog (insulin aspart). Humalog 75/25 and Humulin 50/50, L and U will be deleted from the formulary.

Deleted	New Formulary
Humalog (insulin lispro)	Novolog (insulin aspart)
Humulin L	Novolin N
Humulin U	Novolin R
Humalog 75/25	Novolin 70/30
Humulin 50/50	Lantus (insulin glargine)

PYXIS OVERRIDE LIST

Oral diphenhydramine will be removed from the Pyxis override list. The override list is intended for medications, which if not given to the patient immediately, will cause serious harm. IV diphenhydramine will still remain on the list.

FORMULARY ADDITIONS

Atomoxetine HCl (Strattera®) 10 mg, 18 mg, 25 mg, 40 mg, 60 mg tablets

Atomoxetine, a selective norepinephrine reuptake inhibitor, is the only FDA-approved non-stimulant medication indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD). Of the FDA-approved medications indicated to treat ADHD, only methylphenidate was compared to atomoxetine in a clinical trial. The precise mechanism of action through which atomoxetine exerts its therapeutic effects is unknown. Through ex-vivo uptake and neurotransmitter depletion studies, it is thought to selectively inhibit the pre-synaptic norepinephrine transporter.

The half-life of atomoxetine is 5 hours in extensive metabolizers. The CYP2D6 enzyme is involved in the oxidative metabolism of atomoxetine, which then undergoes glucuronidation. Poor metabolizers of CYP2D6 medications (about 7% of Caucasians and 2% of African Americans) have a slightly different pharmacokinetic profile. They have reduced activity in the CYP2D6 pathway and thus, 10-fold higher AUCs, 5-fold higher peak plasma concentrations and a slower elimination of atomoxetine resulting in a half-life of 24 hours.

In extensive metabolizers with hepatic dysfunction, the AUC is increased 2-fold with moderate (Child-Pugh Class B) hepatic insufficiency and 4-fold with severe hepatic insufficiency (Child-Pugh Class C). Dose adjustment is recommended in these patients. In extensive metabolizers with end stage renal disease or lesser degrees of renal insufficiency, atomoxetine can be administered using the normal dosage regimen.

Coadministration of atomoxetine and systemically administered (oral or intravenous) albuterol (or other B₂-agonists) can potentiate the effects of albuterol on the cardiovascular system. There is an increase in steady-state plasma concentrations of atomoxetine when administered with CYP2D6 inhibitors such as paroxetine, fluoxetine and quinidine. In extensive metabolizers, the exposure increase of atomoxetine is similar to those observed in poor metabolizers. The AUC and C_{ss,max} in extensive metabolizers increases 6 to 8 fold and 3 to 4 fold respectively. In vitro studies show that plasma concentrations of atomoxetine are not increased in poor metabolizers given CYP450 inhibitors. Atomoxetine should be used cautiously with pressor agents because of possible blood pressure side effects.

Atomoxetine has been studied in children 6 years of age and older. There have not been adequate and well-controlled studies conducted in pregnant women. Atomoxetine use is cautioned in nursing women since it is not known whether or not atomoxetine or its metabolites are excreted in human milks. Studies show that atomoxetine and its metabolites are excreted in the milk of rats. Atomoxetine is listed in pregnancy category C.

DRUG AND FOOD INTERACTIONS

The manufacturer's prescribing information lists no food/drug interactions.

DOSAGE AND ADMINISTRATION

Initial treatment in children and adolescents up to 70 kg in body weight should be a total daily dose of approximately 0.5mg/kg. After a minimum of 3 days, it can be increased to a total dose of approximately 1.2mg/kg, given as a single dose in the morning or as evenly divided doses in the morning and late afternoon/early evening. In children and adolescents greater than 70 kg, a total daily dose of 40 mg should be given and subsequently increased after a minimum of 3 days to approximately 80 mg as a single dose or divided evenly as stated above. After 2 to 4 weeks, the dose can be further increased to the recommended maximum total daily dose of 100 mg.

Hepatically impaired patients with Child-Pugh Class B hepatic insufficiency, initial and target doses should be 50% of the normal dose. For those in Class C, the initial and target dose should be 25% of the normal dose.

If a patient is concomitantly on a strong CYP2D6 inhibitor and less than 70 kg, atomoxetine should be dosed at 0.5 mg/kg/day and increased to 1.2 mg/kg/day if symptoms do not improve within 4 weeks and the initial dose is well tolerated. If the patient is more than 70 kg, atomoxetine should be given at 40 mg/day and increased to 80 mg/day only if symptoms do not improve within 4 weeks and the initial dose is well tolerated. (Strong CYP2D6 inhibitors include paroxetine, fluoxetine and quinidine)

Safety and efficacy of single doses over 120 mg and total daily doses over 150 mg have not been evaluated.

Abarelix (Plenaxis™) 100 mg (50mg/mL) for injectable suspension

Abarelix is indicated for the palliative treatment of men with advanced symptomatic prostate cancer, in whom luteinizing hormone release hormone (LHRH) agonist therapy is not appropriate and who refuse surgical castration, and have one or more of the following (1) risk of neurological compromise due to metastases (2) ureteral or bladder outlet obstructions due to local encroachment or metastatic disease, or (3) severe bone pain from skeletal metastases persisting on narcotic analgesia. About 5% of men with prostate cancer could be a candidate for abarelix.

Abarelix is a pure gonadotropin-releasing hormone (Gn-RH) antagonist. It directly suppresses luteinizing hormones (LH) and follicle stimulating hormone (FSH) secretion and thereby reduces the secretion of testosterone by the testes. Unlike the LHRH agonists, it is devoid of any agonist activity on the Gn-RH receptor. Due to the direct inhibition of LH secretion, there is no initial increase in serum testosterone concentrations as seen with the LHRH agonists.

Boxed warnings stated that in a clinical trial of patients with advanced, symptomatic prostate cancer, 3 of 81 patients experienced an immediate-onset systemic allergic reaction after receiving abarelix. The allergic reactions were urticaria (day 15), urticaria and pruritis (day 29), and hypotension and syncope (day 141). Patients should be monitored for at least 30 minutes after each injection of abarelix. In the event of an allergic reaction, appropriate supportive measurements should be taken. Plenaxis may prolong the QT interval and decision needs to be made if the risks outweigh the benefits in patients with baseline QTc > 450 msec, or in patients taking Class IA or Class III antiarrhythmic medications. Clinically meaningful transaminase elevations were observed in some patients. Serum levels should be monitored at baseline and periodically thereafter. Extended treatment may result in a decrease in bone mineral density. There was a greater decreased effectiveness with increased duration of treatment that occurred in patients weighing more than 225 pounds. Strict monitoring of serum testosterone in these patients is warranted.

Abarelix is Pregnancy Category X.

DRUG AND FOOD INTERACTIONS

The manufacturer's prescribing information lists no food/drug interactions.

Dosage and Administration

Because of the increased risk of serious, and potentially life threatening, allergic reactions, abarelix is approved with marketing restrictions. Only physicians and hospital pharmacies enrolled in Praecis's Plenaxis PLUS Program, which requires attestation of qualifications and acceptance of prescribing responsibilities, may prescribe abarelix.

The recommended dose of abarelix is 100 mg administered intramuscularly to the buttock on Day 1, 15, 29, and every 4 weeks thereafter. Treatment failure can be monitored with serum testosterone measurements occurring at Day 29 and every 8 weeks thereafter.

Valsartan (Diovan)

40 mg, 80 mg, 160 mg, 320 mg tablets

Valsartan is an orally active nonpeptide that is indicated for the treatment of hypertension (alone or in combination with other anti-hypertensive agents) and heart failure. By selectively blocking the binding of angiotensin II to the AT₁ receptor in many tissues, valsartan blocks the vasoconstricting and aldosterone-secreting effects of angiotensin II.

The contraindications, warnings, precautions and adverse events for valsartan are similar to those for the entire ARB class.

Valsartan does not interact with the CYP 450 enzyme system. The concomitant use of potassium-sparing diuretics (ex. spironolactone, triamterene, amiloride), potassium supplements or salt substitutes containing potassium may lead to increased levels of serum potassium. In heart failure patients, this may also lead to increased serum creatinine levels. In addition, reversible increases in serum lithium concentrations have been observed.

Valsartan is a pregnancy category C medication in the first trimester and category D in the second and third trimesters. It is not known if valsartan is excreted in human milk, but studies show that valsartan is excreted in the milk of lactating rats. Since there is the potential for adverse effects on the infant, a decision to discontinue nursing or the medication should be made; though the importance of the medication to the mother should be acknowledged.

DRUG AND FOOD INTERACTIONS

Valsartan may be administered with or without food even though administration with food leads to decreased exposure (AUC) and peak plasma concentrations (C_{max}) by 40% and 50% respectively.

Dosage and Administration

Hypertension

The dosage range of valsartan is 80 mg to 320 mg. Starting dose is 80 mg or 160 mg once a day as monotherapy for patients who are not volume-depleted. The anti-hypertensive effect is present within 2 weeks and maximal reduction is generally observed in 4 weeks. The dose may be increased to 320 mg or a diuretic may be administered if additional anti-hypertensive effect is needed. (The addition of a diuretic has a greater effect than dose increases above 80 mg.)

Heart Failure

Valsartan should be initiated at 40 mg twice daily and then titrated to 80 mg and 160 mg twice daily as tolerated by the patient. The maximum daily dose given in clinical trials was 320 mg in divided doses. (Concomitant diuretics may need a reduction in dosage and concomitant use of ACE inhibitors and beta blockers are not recommended.)

THERAPEUTIC EXCHANGE

Lomotil to Loperamide

Loperamide is an antidiarrheal indicated for the treatment of acute and chronic diarrhea associated with irritable bowel disease; chronic idiopathic diarrhea; chronic diarrhea caused by bowel resection or organic lesions; and ileostomy discharge. Proposed mechanisms of action include: direct antiperistaltic action on circular and longitudinal intestinal muscle that prolongs transit time, reduces fecal volume, increases viscosity, and diminishes fluid and electrolyte loss; antisecretory activity inhibiting the calcium-binding protein calmodulin which may regulate chloride secretion.

Loperamide has demonstrated to be effective in the treatment of acute diarrhea. Efficacy data suggest that loperamide is more effective than diphenoxylate. Loperamide is safe with few adverse reactions reported worldwide. It has the advantage of not crossing the blood-brain barrier, thereby reducing the risk for adverse drug reactions. It may be preferred over Lomotil because the atropine component in the latter causes expected side effects of blurred vision, dry mouth and urinary retention. Lomotil is a controlled substance unlike loperamide.

Zaleplon (Sonata) substitution to Temazepam (Restoril)

Zaleplon is a sedative-hypnotic indicated for the short-term treatment of insomnia. Although this agent differs structurally from benzodiazepines, it binds to the benzodiazepine (omega) receptor and acts as a benzodiazepine receptor agonist. Zaleplon has particular selectivity for the central omega (1) binding site. In contrast, other hypnotic benzodiazepines bind nonselectively to omega-1, omega-2 and omega-3 receptors. The clinical significance or relevance of selective binding has not been established and there is no evidence to support that selective binding carries a significant therapeutic benefit. The effects of zaleplon can be completely prevented or reversed by the benzodiazepine antagonist flumazenil. The majority of comparative published data has compared zaleplon to triazolam, flurazepam, and zolpidem.

Although triazolam is most likely the most similar formulary agent in terms of half-life, the use of short half-life benzodiazepines (particularly in the hospitalized patient) may be associated with early morning awakening and falls. **Use of temazepam is recommended as it is the most frequently prescribed (25 fold) hypnotic at KU Med and appears to be the preferred agent by KUMed prescribers.**

There is also a significant cost difference between temezepam (<\$0.10) and zaleplon (>\$1.50).

RENAL DOSING PROTOCOL EXTENDED TO ALL ICUs

The renal dosing protocol has been successfully implemented in the SICU. In a 6- month time-frame, 128 total adjustments have been made as per the protocol and none have been overridden by a physician. This protocol will now be extended to all ICUs. Dialysis patients are exempt from this protocol and pharmacists must contact the physician before making any dosage adjustments for these patients. (FORM 1)

RANGE AND MULTI-ROUTE ORDER POLICY

A new policy was developed regarding range and multi-route orders according to JCAHO standards. This policy separates the use of pain management medication and non-pain management medication. (FORM 2)



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Renal Dosing Protocol for Critical Care Units		

DEFINITIONS

Determination of Renal Function: Creatinine clearance (CrCl) may be measured directly or estimated with the Cockcroft-Gault equation:

$[(140 - \text{age}) \times \text{Actual Body Weight (kg)} / (\text{Serum Cr} \times 72)]$ (multiply the result by 0.85 if female)
Note: Use adjusted body weight in patients more than 20% over ideal body weight.

Note: Serum creatinine or estimated creatinine clearance may be misleading indicators of renal function in certain situations. Calculated clearances may be inaccurate in patients with chronic renal failure, obesity, volume overload, diabetes, low creatinine, hypoalbuminemia, hypermetabolic conditions, advanced age, or debilitation. Renal function may be overestimated in situations associated with rapidly rising serum creatinines, such as hepato-renal syndrome or drug-induced nephrotoxicity. It can also be underestimated in periods of rapidly falling serum creatinine, such as after renal transplant. Urine creatinine clearance measurements may be advisable in these and in oliguric states.

Renal Dosing Protocol Drug List: A list consisting of selected medications that include those with high volume of use, complicated dosing regimens, or medications with past reports of adverse drug reactions when not adjusted for renal impairment. The List contains maintenance dosing regimens intended to establish and maintain therapeutic dosing concentrations, while avoiding excessive accumulation of the drug or its metabolites and minimizing toxicity.

POLICY

The Clinical Pharmacist may write an order to adjust the dose of a medication based on renal function, if warranted, for medications listed on the KU Med Renal Dosing Protocol Drug List. For medications included on the KU Med Renal Dosing Protocol Drug List the adjustment may take place without physician contact.

The KU Med Renal Dosing Protocol Drug List will be maintained by the Pharmacy and Therapeutics Committee and all revisions of the List will be subject to Committee approval.

Dose adjustments will not be made without physician contact for medications ordered “dose as written” or other equivalent order. Medication loading doses will not be automatically adjusted based on the protocol.

DIRECTOR OF PHARMACY

REVIEW:

CHAIR OF PHARMACY & THERAPEUTICS COMMITTEE

_____/_____/_____
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Renal Dosing Protocol for Critical Care Units		

PROCEDURES

1. Each patient's drug therapy will be reviewed to determine proper dosing for renal function. If a serum creatinine is not available, the pharmacist may order a serum creatinine concentration based on his/her clinical judgment for its need.
2. These guidelines must be used in conjunction with clinical evaluation. Factors to consider include age, body weight, drug interactions, hepatic insufficiency, or other concurrent disease states. The severity, type, and site of infection, host immunocompetency, as well as the results of cultures and susceptibilities influence administration of antibiotics. If the renal service is consulting, discussion with that service should take place before any dosage changes are made.
3. For patients receiving medications included on the Renal Dosing Protocol Medication List, the clinical pharmacist will convert the prescribed dose to one consistent with the patient's renal function if necessary. The Clinical Pharmacist will:
 - Use a standardized sticker or write an order with equivalent content on the official physician's order form in the medical record (i.e. patient's chart) changing the order to the appropriate dose, stating "Per Renal Dosing Protocol."
 - Note the change as part of medication order entry in the pharmacy computer system so that evidence of the renal dosing adjustment will appear on the computer-generated medication administration record (MAR).
4. This dose conversion may be overridden, at any time, by the prescriber writing "Dose as Written" or other equivalent orders with the medication order. If the prescriber indicated "Dose as Written" on the original order, this must be indicated on the entry in the patient's medication administration record (MAR) when the order is transcribed or entered.

DIRECTOR OF PHARMACY

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_____/_____/_____
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THE UNIVERSITY
OF KANSAS HOSPITAL
KUMED

EFFECTIVE DATE:
09/04

**DEPARTMENT OF PHARMACY
POLICY & PROCEDURE**

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PRESCRIBING/TRANSCRIBING

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Range and Multi-Route Orders

POLICY

Range orders are commonly used to allow for adjustment of a patient's therapy based on clinical conditions and parameters established by the physician. Range orders will be carried out in accordance with the following procedure in order to ensure that these orders are used in a safe and effective manner.

PROCEDURE

When an order includes a range of dose and frequency, the instruction on how the nurse determines what dose or time frame in which to administer the dose should be included in the physician's order. In the absence of such instructions, the nurse has the authority, based on patient assessment, to adjust medication levels within the dosage and frequency ranges stipulated by the prescriber and according to the following protocol:

1. Range orders (for pain management)
 - a. Ranges in frequency

The shortest time interval will be used to reassess the need for the next dose. Once a dosing interval has been established for the patient's specific need, the interval for reassessment can be extended toward the longer time interval that was ordered.

- b. Ranges in dosage

Prior to the administration of a PRN pain medication, the patient's pain will be assessed. Unless otherwise specified in the physician's order, the nurse will determine the necessary dosage to be administered using the following guideline:

Pain Score	Action
1 to 3 (mild)	Administer lowest dosage in the prescribed dosage range
4 to 7 (moderate)	Administer middle dosage (if applicable); otherwise, administer the lowest dosage that has been effective; therapy should be initiated at the lowest prescribed dosage and escalated upward as needed
8 to 10 (severe)	Administer the highest dosage in the prescribed dosage range

- c. Dose of medication less than the range prescribed
Doses less than the ordered range cannot be given (e.g., administering 2 mg of morphine when the order was written for 4-8 mg). The prescriber must write a new order to administer a dose lower than the range previously specified.

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d. Prescriber contact

If the nurse suspects the patient is being over-treated or under-treated using this guideline, the prescriber should be contacted to reassess the patient's needs.

2. Range orders (for indications other than pain management)

a. Determining dosage of PRN medications

The nurse will administer the PRN medication initially using the lowest dose and shortest time frame ordered by the physician. If symptoms appear before the next dose without the presence of adverse effects, the dose can be increased to the maximum available within the ordered range. A new order will be required if the maximum prescribed dose has been administered and additional doses are needed before the next dosing interval time.

b. Determining frequency of PRN medications

When the order includes a time range, the order should be treated as if it is written at the lower limit of the ordered range.

3. PRN medications with multiple indications

Indication for PRN use must be included as a part of the physician order for all PRN medications that have two or more possible indications (e.g., acetaminophen, diphenhydramine).

4. Determination of multi-route orders

If the patient is taking oral medication or oral intake without complications, the nurse will give oral PRN medications unless the medication is only dispensed in intravenous form.

PRN medications will be given intravenously or intramuscularly until the patient is taking fluids by mouth without complications.

Intravenous is the preferred route of administration for orders written as "intramuscularly or intravenously".

The nurse's assessment of the patient may act as an exception. Factors such as the condition and function of the gastrointestinal tract, allergies, and the patient's preference of PRN ordered medications might influence the route of administration.

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5. Examples of range order interpretation

Example #1: Dosage and frequency ranges

Oxycodone 5 mg / Acetaminophen 325 mg 1-2 tabs po q 4-6 hours PRN pain (pain score = 5)

- Initially, the patient may receive 1 tablet
- The patient's pain must be reassessed prior to administration of any additional doses
- If the desired effect is not achieved and no adverse reactions have been observed after the initial dose, the patient may receive 2 tablets every four hours as needed for pain

Example #2: Dosage range without frequency range

Promethazine 12.5-25 mg po q 6 hours PRN nausea

- Initially, the patient may receive 12.5 mg every six hours as needed for nausea
- If the desired effect is not achieved and no adverse reactions have been observed after the initial dose, the patient may receive 25 mg every six hours as needed for nausea

Example #3: Frequency range without dosage range

Morphine sulfate 2 mg q 3-4 hours PRN pain

- The patient may receive 2 mg every three hours as needed for pain
- If the desired effect is not achieved at the shortest dosing interval (i.e., 3 hours), the nurse should contact the prescriber to notify them of the need for reassessment

Example #4: Wide dose ranges

Morphine sulfate 2-8 mg q 2-4 hours PRN pain (pain score = 8)

- Initially, the patient may receive 8 mg
- The patient's pain must be reassessed prior to administration of any additional doses

Example #5: Orders with multiple routes

Diphenhydramine 25 mg IV/PO q 6 hours PRN itching

- Initially, the patient may receive 25 mg every six hours orally if they are taking oral medications or oral intake without complications

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Formulary Additions and Deletions (January 1, 2004 - Present)

Generic Name	Trade Name	Therapeutic Class	Action	Date	Comments
Abarelix	Plenaxis	Palliative Agent	Added	9/28/04	
Atomoxetine	Strattera	Non-stimulant ADHD medication	Added	9/28/04	
BCNU Wafers	Gliadel	Chemotherapeutic	Added	2/26/04	
Brompheniramine	N/A	Antihistamine	Deleted	3/19/04	
Brompheniramine/ Phenylpropanolamine	N/A	Antihistamine/ Decongestant	Deleted	3/19/04	
Darbepoetin Alfa	Aranesp	Hematopoietic Agent	Deleted	6/24/2004	
DTaP, Hep B (Recombinant), and IPV Combined	Pediarix	Vaccine	Added	5/27/04	
Doxorubicin HCl Liposomal	Doxil	Chemotherapeutic	Added	5/27/04	
Guaifenesin/ Codeine	N/A	Expectorant	Added	1/22/04	
Halothane	N/A	Inhalational Anesthetic	Deleted	3/25/04	
Insulin	Humalog 75/25	Antidiabetic	Deleted	9/28/04	See Oct Pharmacy Key
Insulin	Humulin	Antidiabetic	Deleted	7/27/04	
Insulin	Lente	Antidiabetic	Deleted	9/28/04	See Oct Pharmacy Key
Insulin	Novolin	Antidiabetic	Added	7/27/04	
Insulin	Novolin 70/30	Antidiabetic	Added	9/28/04	See Oct Pharmacy Key
Insulin	Ultralente	Antidiabetic	Deleted	9/28/04	See Oct Pharmacy Key
Lansoprazole IV	Prevacid	Proton Pump Inhibitor	Added	7/27/04	See guidelines for use
Lidocaine 5%	Lidoderm	Local Anesthetic	Added	8/28/03	
Mivacurium	Mivacron	Neuromuscular Blocker	Added	2/26/04	
Morphine Extended Release	Avinza	Narcotic Analgesic	Added	4/29/04	See guidelines for use
Moxifloxacin	Avelox	Antibiotic	Deleted	6/24/04	
Nateglinide	Starlix	Antidiabetic	Added	4/29/04	
Olanzapine for Injection	Zyprexa IntraMuscular	Antipsychotic	Added	6/24/04	See guidelines for use
Oseltamivir	Tamiflu	Antiviral	Added	3/25/04	
Pantoprazole IV	Protonix	Proton Pump Inhibitor	Deleted	7/27/2004	See guidelines for use
Pravastatin	Pravahol	HMG-CoA Reductase Inhibitor	Added	7/27/2004	
Risperidone Long-Acting	Risperdal Consta	Antipsychotic	Added	2/26/04	See guidelines for use
Rofecoxib	Vioxx	COX-2 Inhibitor	Deleted	9/30/04	Withdrawn from Market
Tiotropium	Spiriva	Anticholinergic	Added	7/27/2004	
Valsartan	Diovan	Angiotensin Receptor Blocker	Added	9/28/2004	See Oct Pharmacy Key
Zonisamide	Zonegran	Antiepileptic	Added	2/26/04	