

# Shopping Around for Diabetes Meds Pays Off

BY MIRIAM E. TUCKER

NEW ORLEANS — Prescription plans offered by large discount stores could save diabetes patients at least \$85 per month in out-of-pocket expenses compared with local chain or independent pharmacies, a cost analysis found.

Previous data suggest that one in every five U.S. patients with diabetes cuts back on medications because of cost. Recent-

ly, large retail stores such as Wal-Mart, Target, and Kmart have launched programs that offer generic medications at much lower cost to customers than that of other types of pharmacies.

An analysis of medical and pharmaceutical claims from the PharMetrics patient-centric database on 52 million unique insured patients from 91 health plans across the United States confirms that these programs can save patients a

significant amount of money out-of-pocket, Dr. Clifton M. Jackness and Dr. Ronald Tamler reported in a poster at the annual scientific sessions of the American Diabetes Association.

“The purpose of our study was to increase physician and patient awareness that there are significant price differences among pharmacies, and that cost is a significant barrier to patient compliance,” Dr. Jackness said in an interview.

“Doctors and patients should work together to find the best pharmacy that serves their needs, and some smaller pharmacies may be able to compete with Wal-Mart’s prices. However, Wal-Mart, Target, and Kmart are full-service pharmacies that answer patient questions, ask about interactions, and keep computerized records on all drugs prescribed through their stores,” added Dr. Jackness, an internist at Mount Sinai School of Medicine, New York.

He and Dr. Tamler, an endocrinologist at Mount Sinai, analyzed claims for the 10 most commonly prescribed medications for all adults younger than age 65 years with a diagnosis of diabetes (ICD-9 code 250) prior to Jan. 1, 2005. The 10 drugs included in the analysis were metformin, atorvastatin, lisinopril, rosiglitazone, furosemide, pioglitazone, simvastatin, hydrochlorothiazide, insulin glargine, and amlodipine. The average number of medications taken by a patient with diabetes is 8.9, according to the investigators.

Some generic drugs offered by Wal-Mart, Target, and Kmart cost much less than the same drugs sold by other pharmacies, while other medications were similar in price. For nongeneric medications, those three discounters, www.drugstore.com, and Medco by Mail seemed to be more competitive than the neighborhood retailers and chains.

For example, the 30-day out-of-pocket cost for generic metformin (500 mg) ranged from \$4.00 at Wal-Mart and Target to \$39.99 at Rite-Aid. For lisinopril (10 mg), the range was \$4.00 at the same two big retailers to \$36.95 at a local pharmacy. But atorvastatin (10 mg)—not available generically as of August 2008—was expensive just about everywhere, ranging from Wal-Mart’s low of \$71.63 to a high of \$107.10 at drugstore.com, not including shipping costs. But added up, the price of all 10 medications was lowest at Medco by Mail (\$428.35), not including shipping. Next lowest was Wal-Mart (\$432.53), while the highest was a local pharmacy (\$639.30), a difference of more than \$200 per month.

The superstores and mail-order firms did not always have the lowest price for every medication, but a patient who bought all 10 prescriptions at one of these stores would save a minimum of \$85 per month, compared with the local chain or independent pharmacy, neither of which had the lowest price for any of the medications included in the analysis, Dr. Jackness and Dr. Tamler said.

Physicians should find out if the medications they prescribe are available as generics and are on the formularies for the low-cost programs. “All the data suggest that [outcomes] would improve if patients could afford their medications,” Dr. Jackness said during the interview.

Neither Dr. Jackness nor Dr. Tamler had any disclosures or conflicts of interest. The PharMetrics prescribing data came from Eli Lilly & Co. representatives, but they did not request compensation for that database. ■



## LIDODERM® (Lidocaine Patch 5%)

### Rx only

**Brief Summary** (For full Prescribing Information refer to package insert.)

### INDICATIONS AND USAGE

LIDODERM is indicated for relief of pain associated with post-herpetic neuralgia. It should be applied only to **intact skin**.

### CONTRAINDICATIONS

LIDODERM is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

### WARNINGS

#### Accidental Exposure in Children

Even a used LIDODERM patch contains a large amount of lidocaine (at least 665 mg). The potential exists for a small child or a pet to suffer serious adverse effects from chewing or ingesting a new or used LIDODERM patch, although the risk with this formulation has not been evaluated. It is important for patients to **store and dispose of LIDODERM out of the reach of children, pets, and others.** (See HANDLING AND DISPOSAL)

#### Excessive Dosing

Excessive dosing by applying LIDODERM to larger areas or for longer than the recommended wearing time could result in increased absorption of lidocaine and high blood concentrations, leading to serious adverse effects (see ADVERSE REACTIONS, Systemic Reactions). Lidocaine toxicity could be expected at lidocaine blood concentrations above 5 µg/mL. The blood concentration of lidocaine is determined by the rate of systemic absorption and elimination. Longer duration of application, application of more than the recommended number of patches, smaller patients, or impaired elimination may all contribute to increasing the blood concentration of lidocaine. With recommended dosing of LIDODERM, the average peak blood concentration is about 0.13 µg/mL, but concentrations higher than 0.25 µg/mL have been observed in some individuals.

### PRECAUTIONS

#### General

**Hepatic Disease:** Patients with severe hepatic disease are at greater risk of developing toxic blood concentrations of lidocaine, because of their inability to metabolize lidocaine normally.

**Allergic Reactions:** Patients allergic to para aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine. However, LIDODERM should be used with caution in patients with a history of drug sensitivities, especially if the etiologic agent is uncertain.

**Non-intact Skin:** Application to broken or inflamed skin, although not tested, may result in higher blood concentrations of lidocaine from increased absorption. LIDODERM is only recommended for use on intact skin.

**Eye Exposure:** The contact of LIDODERM with eyes, although not studied, should be avoided based on the findings of severe eye irritation with the use of similar products in animals. If eye contact occurs, immediately wash out the eye with water or saline and protect the eye until sensation returns.

### Drug Interactions

**Antiarrhythmic Drugs:** LIDODERM should be used with caution in patients receiving Class I antiarrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and potentially synergistic.

**Local Anesthetics:** When LIDODERM is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

### Carcinogenesis, Mutagenesis, Impairment of Fertility

**Carcinogenesis:** A minor metabolite, 2, 6-xylylidine, has been found to be carcinogenic in rats. The blood concentration of this metabolite is negligible following application of LIDODERM.

**Mutagenesis:** Lidocaine HCl is not mutagenic in Salmonella/mammalian microsome test nor clastogenic in chromosome aberration assay with human lymphocytes and mouse micronucleus test.

**Impairment of Fertility:** The effect of LIDODERM on fertility has not been studied.

### Pregnancy

**Teratogenic Effects: Pregnancy Category B.** LIDODERM (lidocaine patch 5%) has not been studied in pregnancy. Reproduction studies with lidocaine have been performed in rats at doses up to 30 mg/kg subcutaneously and have revealed no evidence of harm to the fetus due to lidocaine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, LIDODERM should be used during pregnancy only if clearly needed.

### Labor and Delivery

LIDODERM has not been studied in labor and delivery. Lidocaine is not contraindicated in labor and delivery. Should LIDODERM be used concomitantly with other products containing lidocaine, total doses contributed by all formulations must be considered.

### Nursing Mothers

LIDODERM has not been studied in nursing mothers. Lidocaine is excreted in human milk, and the milk: plasma ratio of lidocaine is 0.4. Caution should be exercised when LIDODERM is administered to a nursing woman.

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### Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

### ADVERSE REACTIONS

#### Application Site Reactions

During or immediately after treatment with LIDODERM (lidocaine patch 5%), the skin at the site of application may develop blisters, bruising, burning sensation, depigmentation, dermatitis, discoloration, edema, erythema, exfoliation, irritation, papules, petechia, pruritus, vesicles, or may be the locus of abnormal sensation. These reactions are generally mild and transient, resolving spontaneously within a few minutes to hours.

#### Allergic Reactions

Allergic and anaphylactoid reactions associated with lidocaine, although rare, can occur. They are characterized by angioedema, bronchospasm, dermatitis, dyspnea, hypersensitivity, laryngospasm, pruritus, shock, and urticaria. If they occur, they should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

#### Other Adverse Events

Due to the nature and limitation of spontaneous reports in postmarketing surveillance, causality has not been established for additional reported adverse events including:

Asthenia, confusion, disorientation, dizziness, headache, hyperesthesia, hypoesthesia, lightheadedness, metallic taste, nausea, nervousness, pain exacerbated, paresthesia, somnolence, taste alteration, vomiting, visual disturbances such as blurred vision, flushing, tinnitus, and tremor.

#### Systemic (Dose-Related) Reactions

Systemic adverse reactions following appropriate use of LIDODERM are unlikely, due to the small dose absorbed (see CLINICAL PHARMACOLOGY, Pharmacokinetics). Systemic adverse effects of lidocaine are similar in nature to those observed with other amide local anesthetic agents, including CNS excitation and/or depression (light-headedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold, or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, and arrest). Excitatory CNS reactions may be brief or not occur at all, in which case the first manifestation may be drowsiness merging into unconsciousness. Cardiovascular manifestations may include bradycardia, hypotension, and cardiovascular collapse leading to arrest.

### OVERDOSAGE

Lidocaine overdose from cutaneous absorption is rare, but could occur. If there is any suspicion of lidocaine overdose (see ADVERSE REACTIONS, Systemic Reactions), drug blood concentration should be checked. The management of overdose includes close monitoring, supportive care, and symptomatic treatment. Dialysis is of negligible value in the treatment of acute overdose with lidocaine.

In the absence of massive topical overdose or oral ingestion, evaluation of symptoms of toxicity should include consideration of other etiologies for the clinical effects, or overdosage from other sources of lidocaine or other local anesthetics.

The oral LD<sub>50</sub> of lidocaine HCl is 459 (346-773) mg/kg (as the salt) in non-fasted female rats and 214 (159-324) mg/kg (as the salt) in fasted female rats, which are equivalent to roughly 4000 mg and 2000 mg, respectively, in a 60 to 70 kg man based on the equivalent surface area dosage conversion factors between species.

### DOSAGE AND ADMINISTRATION

Apply LIDODERM to intact skin to cover the most painful area. Apply up to three patches, only once for up to 12 hours within a 24-hour period. Patches may be cut into smaller sizes with scissors prior to removal of the release liner. (See HANDLING AND DISPOSAL) Clothing may be worn over the area of application. Smaller areas of treatment are recommended in a debilitated patient, or a patient with impaired elimination.

If irritation or a burning sensation occurs during application, remove the patch (es) and do not reapply until the irritation subsides.

When LIDODERM is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

### HANDLING AND DISPOSAL

Hands should be washed after the handling of LIDODERM, and eye contact with LIDODERM should be avoided. Do not store patch outside the sealed envelope. Apply immediately after removal from the protective envelope. Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them. LIDODERM should be kept out of the reach of children.

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature].

Manufactured for:

Endo Pharmaceuticals Inc.  
Chadds Ford, Pennsylvania 19317



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