

Discount Card's Woes Offer Lessons for CMS

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The experience of the drug discount card program that Medicare beneficiaries participated in prior to the launch of the Medicare drug benefit offers some lessons for the Centers for Medicare and Medicaid Services, the Government Accountability Office said in two reports.

In its first report, the GAO said that although the Centers for Medicare and Medicaid Services (CMS) had identified and corrected some problems with the entities that sponsored the drug cards, it also "had some limitations with respect to the timeliness of oversight activities and the guidance provided to sponsors."

For instance, the report noted, "CMS finalized guidance on how drug card sponsors should report data on price concessions from manufacturers and pharmacies in November 2004, about 5 months after the program began. According to CMS, as

of August 2005, the overall quality of that data remained questionable, with problems such as outliers and missing data."

The report also noted that a CMS contractor requested two preenrollment information packets from six drug card sponsors.

"All the packets were noncompliant with program requirements," the report said. "Most packets were missing materials required by CMS and some materials had not been previously approved for distribution

by the CMS contractor. The contractor never received several requested packets." CMS told the GAO that it had worked with the sponsors to resolve the problems.

For its part, CMS said in a letter to the GAO that the report "did not paint a full picture of the depth and breadth of the actual monitoring and oversight activities." Dr. Mark B. McClellan, CMS administrator, acknowledged that with the discount card program, "we have learned many valuable lessons that will inform our future efforts as we plan for the drug benefit in 2006."

The second report looked at CMS's beneficiary and outreach education efforts for the discount card program. In general, the GAO found that "CMS's efforts did not consistently provide information that was clear, accurate, and accessible, and they collectively fell short of conveying program features." The report did add, however, that the GAO

got this impression by looking at assessments that CMS has done on its own programs, and "these assessments acknowledge the actions taken by CMS to address some of these problems."

In spite of CMS's outreach efforts, the report said, "beneficiaries confused the drug card with the 2006 prescription drug benefit, and some beneficiaries did not enroll because they were under the impression that Medicare would be sending them a card. Furthermore, the concept of a private drug card sponsor was difficult for many beneficiaries to understand."

Beneficiaries also were confused about eligibility, the report said. "Many beneficiaries incorrectly thought that the drug card was only for low-income people, and those who likely qualified for the \$600 in transitional assistance did not believe they qualified for it, even after having the income criteria explained to them," the report noted.

In response to the second report, Dr. McClellan said that it, like the first report, did not address the "full picture of the depth and breadth of the actual activities undertaken." The number of education and outreach activities was "unprecedented for a program of limited duration," he added.

As he did in responding to the first report, Dr. McClellan said that the lessons learned from this portion of the discount card program would be applied to the drug benefit. But he also added, "From a public service perspective, the most important question about the drug discount card is whether the program provided discounts and access to prescription drugs for any beneficiary who wanted help. The answer is yes, immediately." ■

The reports are available at www.gao.gov.

BRIEF SUMMARY

SOLARAZE® GEL

Rx Only

Diclofenac Sodium-3%

FOR DERMATOLOGIC USE ONLY. NOT FOR OPHTHALMIC USE.

INDICATIONS AND USAGE

Solaraze® (diclofenac sodium) Gel is indicated for the topical treatment of actinic keratoses (AK). Sun avoidance is indicated during therapy.

CLINICAL STUDIES

Clinical trials were conducted involving a total of 427 patients (213 treated with Solaraze® and 214 with a gel vehicle). Each patient had no fewer than five AK lesions in a major body area, which was defined as one of five 5 cm x 5 cm regions: scalp, forehead, face, forearm and hand. Up to three major body areas were studied in any patient. All patients were 18 years of age or older (male and female) with no clinically significant medical problems outside of the AK lesions and had undergone a 60-day washout period from disallowed medications (masoprocol, 5-fluorouracil, cyclosporine, retinoids, trichloroacetic acid/lactic acid/peel, 50% glycolic acid peel) and hyaluronan-containing cosmetics. Patients were excluded from participation for reasons of known or suspected hypersensitivity to any Solaraze® ingredient, pregnancy, allergies to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs), or other dermatological conditions which might affect the absorption of the study medication. Application of dermatologic products such as sunscreens, cosmetics, and other drug products was not permitted. Patients were instructed to apply a small amount of Solaraze® Gel (approximately 0.5 g) onto the affected skin, using their fingers, and gently smoothing the gel over the lesion. In addition, all patients were instructed to avoid sun exposure. Complete clearing of the AK lesions 30 days after completion of treatment was the primary efficacy variable. No long-term patient follow-ups, after the 30-day assessments, were performed for the detection of recurrence.

Complete Clearance of Actinic Keratosis Lesions 30 Days Post-Treatment (all locations)			
	Solaraze® Gel	Vehicle	p-value
Study 1 90 days treatment	27/58 (47%)	11/59 (19%)	<0.001
Study 2 90 days treatment	18/53 (34%)	10/55 (18%)	0.061
Study 3 60 days treatment	15/48 (31%)	5/49 (10%)	0.021
Study 3 30 days treatment	7/49 (14%)	2/49 (4%)	0.221

CONTRAINDICATIONS

Solaraze® (diclofenac sodium) Gel is contraindicated in patients with a known hypersensitivity to diclofenac, benzyl alcohol, polyethylene glycol monomethyl ether 350 and/or hyaluronate sodium.

WARNINGS

As with other NSAIDs, anaphylactoid reactions may occur in patients without prior exposure to diclofenac. Diclofenac sodium should be given with caution to patients with the aspirin triad. The triad typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs.

PRECAUTIONS

General

Solaraze® (diclofenac sodium) Gel should be used with caution in patients with active gastrointestinal ulceration or bleeding and severe renal or hepatic impairments. Solaraze® should not be applied to open skin wounds, infections, or exfoliative dermatitis. It should not be allowed to come in contact with the eyes.

The safety of the concomitant use of sunscreens, cosmetics or other topical medications and Solaraze® is unknown.

Information for Patients

In clinical studies, localized dermal side effects such as contact dermatitis, exfoliation, dry skin and rash were found in patients treated with Solaraze® at a higher incidence than in those with placebo.

If severe dermal reactions occur, treatment with Solaraze® may be interrupted until the condition subsides. Exposure to sunlight and the use of sunlamps should be avoided.

Safety and efficacy of the use of Solaraze® together with other dermal products, including cosmetics, sunscreens, and other topical medications on the area being treated, have not been studied.

Drug Interactions

Although the systemic absorption of Solaraze® is low, concomitant oral administration of other NSAIDs such as aspirin at anti-inflammatory/analgesic doses should be minimized.

Carcinogenesis, Mutagenesis, Impairment of Fertility

There did not appear to be any increase in drug-related neoplasms following daily topical applications of diclofenac sodium gel for 2 years at concentrations up to 0.035% diclofenac sodium and 2.5% hyaluronate sodium in albino mice.

A photocarcinogenicity study with up to 0.035% diclofenac in the Solaraze® vehicle gel was conducted in hairless mice at topical doses up to 2.8 mg/kg/day. Median tumor onset was earlier in the 0.035% group (Solaraze® contains 3% diclofenac sodium).

Diclofenac was not genotoxic in *in vitro* point mutation assays in mammalian mouse lymphoma cells and Ames microbial test systems, or when tested in mammalian *in vivo* assays including dominant lethal and male germinal epithelial chromosomal studies in

mice, and nucleus anomaly and chromosomal aberration studies in Chinese hamsters. It was also negative in the transformation assay utilizing BALB/3T3 mouse embryo cells.

Fertility studies have not been conducted with Solaraze® Gel. Diclofenac sodium showed no evidence of impairment of fertility after oral treatment with 4 mg/kg/day (7 times the estimated systemic human exposure) in male or female rats.

* Based on body surface area and assuming 10% bioavailability following topical application of 2 g Solaraze® Gel per day (1 mg/kg diclofenac sodium).

Pregnancy:

Teratogenic Effects: Pregnancy Category B

The safety of Solaraze® (diclofenac sodium) Gel has not been established during pregnancy. However, reproductive studies performed with diclofenac sodium alone at oral doses up to 20 mg/kg/day (15 times the estimated systemic human exposure*) in mice, 10 mg/kg/day (15 times the estimated systemic human exposure) in rats, and 10 mg/kg/day (30 times the estimated systemic human exposure) in rabbits have revealed no evidence of teratogenicity despite the induction of maternal toxicity. In rats, maternally toxic doses were associated with dystocia, prolonged gestation, reduced fetal weights and growth, and reduced fetal survival.

* Based on body surface area and assuming 10% bioavailability following topical application of 2 g Solaraze® Gel per day (1 mg/kg diclofenac sodium).

Diclofenac has been shown to cross the placental barrier in mice and rats. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should not be used during pregnancy unless the benefits to the mother justify the potential risk to the fetus. Because of the risk to the fetus resulting in premature closure of the ductus arteriosus, diclofenac should be avoided in late pregnancy.

Labor and Delivery

The effects of diclofenac on labor and delivery in pregnant women are unknown. Because of the known effects of prostaglandin-inhibiting drugs on the fetal cardiovascular system (closure of the ductus arteriosus), use of diclofenac during late pregnancy should be avoided and, as with other nonsteroidal anti-inflammatory drugs, it is possible that diclofenac may inhibit uterine contractions and delay parturition.

Nursing Mothers

Because of the potential for serious adverse reactions in nursing infants from diclofenac sodium, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Actinic keratosis is not a condition seen within the pediatric population. Solaraze® should not be used by children.

Geriatric Use

No overall differences in safety or effectiveness were observed between geriatric subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

Of the 423 patients evaluable for safety in adequate and well-controlled trials, 211 were treated with Solaraze® drug product and 212 were treated with a vehicle gel. Eighty-seven percent (87%) of the Solaraze®-treated patients (183 patients) and 84% of the vehicle-treated patients (178 patients) experienced one or more adverse events (AEs) during the studies. The majority of these reactions were mild to moderate in severity and resolved upon discontinuation of therapy.

Of the 211 patients treated with Solaraze®, 172 (82%) experienced AEs involving skin and the application site compared to 160 (75%) vehicle-treated patients. Application site reactions (ASRs) were the most frequent AEs in both Solaraze® and vehicle-treated groups. Of note, four reactions, contact dermatitis, rash, dry skin and exfoliation (scaling) were significantly more prevalent in the Solaraze® group than in the vehicle-treated patients.

Eighteen percent of Solaraze®-treated patients and 4% of vehicle-treated patients discontinued from the clinical trials due to adverse events (whether considered related to treatment or not). These discontinuations were mainly due to skin irritation or related cutaneous adverse reactions.

OVERDOSAGE

Due to the low systemic absorption of topically-applied Solaraze® Gel, overdosage is unlikely. There have been no reports of ingestion of Solaraze®. In the event of oral ingestion, resulting in significant systemic side effects, it is recommended that the stomach be emptied by vomiting or lavage. Forced diuresis may theoretically be beneficial because the drug is excreted in the urine.

DOSAGE AND ADMINISTRATION

Solaraze® Gel is applied to lesion areas twice daily. It is to be smoothed onto the affected skin gently. The amount needed depends upon the size of the lesion site. Assure that enough Solaraze® Gel is applied to adequately cover each lesion. Normally 0.5 g of gel is used on each 5 cm x 5 cm lesion site. The recommended duration of therapy is from 60 days to 90 days. Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy. Lesions that do not respond to therapy should be carefully re-evaluated and management reconsidered.

Manufactured by: Patheon Inc., Toronto, Ontario, Canada.

Manufactured for:

DERMarts DIVISION
DOAK DERMATOLOGICS
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