

## Walgreens promotes colon cancer education

By AMANDA BALTAZAR

DEERFIELD, Ill. — Walgreens is partnering with the Colon Cancer Alliance to educate consumers about colon cancer and encourage them to seek screening for the disease.

Timed to coincide with Colorectal Cancer Awareness Month, Walgreens' initiative features in-store informational posters, brochures and information on prescription labels and in circulars. Pharmacists also are available to talk to consumers about colon cancer and the screening process.

Since Walgreens' 6,200 stores attract about 5 million customers a day nationwide, this program is likely to have a big impact during its March through April run, said Nimesh Jhaveri, director of pharmacy services

for Walgreens.

Colon cancer is the second-leading cause of death from cancer in the United States. Every four minutes a person is diagnosed with it, meaning 154,000 Americans annually. And 55,000 people die of the disease every year—one person every nine minutes, 85 percent of them over age 50. In 2003, the United States spent more than \$6.5 billion treating the disease.

These numbers have been fairly steady for several years now, according to Tim Turnham, chief executive officer of the Colon Cancer Alliance, "but if everyone were screened, they would plummet," he said. In fact, he added, 80 percent of cases would be caught in time if everyone were screened.

Screening can stop the spread of this disease and save

CONTINUED ON PAGE 38



This year's colon cancer screening promotion at Walgreens features bigger signage, more brochures and bilingual information.

## Kerr

CONTINUED FROM PAGE 20

Kerr is an active participant in an MTM program, CheckMeds NC, launched October 2007 by North Carolina Lt. Gov. Beverly Perdue and supported by the NC Health and Wellness Trust Fund. One of the purposes of CheckMeds NC is to help ensure that patients take their prescribed and over-the-counter medications appropriately. Since the program was launched, Kerr's pharmacists have conducted more than 2,000 comprehensive

medication reviews with patients in the program, the company reports. CheckMeds NC is available to any North Carolina senior who has a Medicare drug benefit, which makes it more available than other medication therapy management programs.

"By far, the best aspect of providing MTM services is the patient response. It is amazing how much difference in quality of life a single comprehensive medication review can make," Brown said. "As pharmacists, our academic training is intensively focused

on optimizing medication therapy.

"Seeing us in this role seems to be a real eye-opener for some patients," she added. "They love it—and we love being able to do what we are trained to do."

Another plaudit for the chain came from the American Diabetes Association, which has named Kerr the 2008 American Diabetes Association Provider of the Year for North Carolina. The award was presented March 1 at the ADA's fifth annual Investing in the Cure ceremony in Durham, N.C.

"Kerr Drug began an evolution of community pharmacy practice as a home for delivery of clinical patient care services," the company noted. "The Kerr Drug Diabetes Education Program is a hallmark of this evolution."

Rebecca Chater, Kerr's director of clinical services, described the event as "a wonderful evening attended by hundreds of healthcare providers and community advocates."

In yet another clinical care initiative, Kerr is partnering with CapMed, a division of Bio-Imaging Technologies that provides interactive personal health information, to launch the second phase of a six-month, personal health record demonstration project. Other participants in the project include SureScripts, the electronic prescribing platform provider; the North Carolina Healthcare Information and Communications Alliance; and other healthcare stakeholders.

The goal, according to CapMed, is to help patients access their own medication histories "to improve patients' compliance with medication therapy, enhance patient-provider communications and to engage patients through personalized messaging and content to im-

prove overall health management." Project participants include patients who were prescribed statin drugs or angiotensin receptor blockers.

In phase one of the project, eligible patients received invitations to join the study from their Kerr pharmacy. In the second phase of the pilot program, patients' personal physicians extended the invitations.

"In addition to other objectives, this research will investigate the impact that the point of engagement has on patient participation," noted CapMed in a statement. Patients in the program are using the CapMed Personal HealthKey, a portable PHR that uses USB flash drive technology and enables users to store, manage and communicate their personal health information with the portable drive.

"The study reveals the critical role of the pharmacist in patient communication, compliance and education," Chater said. "Kerr pharmacists will authenticate patients to receive medication history information, provide them with CapMed Personal HealthKeys, deliver education alerts and reminders and facilitate information dissemination between patients using the HealthKey and their providers."

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# Walgreens

CONTINUED FROM PAGE 26

lives, but many people are not screened—often due to

perceived unpleasantness or simply embarrassment.

“It’s one of those diseases that you tend to forget about because it’s not sexy to talk

about it,” Jhaveri said. “Half the battle is just being comfortable to have these types of discussions. Just the notion of a colonoscopy makes people

very uncomfortable. But it’s a very simple procedure now, and people don’t realize that.” “The program with Walgreens makes we’re get-

ting this not-talked-about disease out there,” Turnham said. “Walgreens is a trusted name, so there’s left behind them endorsing this.”

Walgreens is confident that it can make a difference, and expects that the in-store materials will prompt customers to talk to the pharmacists. “It’s about understanding that the risk is there,” Jhaveri said.

“There is no downside to doing this,” he explained. “Pharmacists get overloaded with mundane tasks. But their knowledge is extremely high, and this helps engage them with the consumer.”

The partnership, which is supported by Salix Pharmaceuticals, also includes a toll-free hotline, manned by CCA experts, and a Web site ([www.walgreens.com/crc](http://www.walgreens.com/crc)), which offers privacy to customers who prefer not to discuss the issue in stores.

The program ran for the first time last year as a test. Walgreens learned that pharmacists wanted more materials and wanted information ahead of time, so they could prepare to advise consumers, Jhaveri said.

Receiving the information in advance also encourages pharmacists to update their knowledge of this disease. It is part of their ongoing continuing education, and the information is available for them online and in stores, both electronically and in paper version.

This year’s program is bigger and more comprehensive, Turnham explained. There’s more and bigger signage, more brochures, information in Spanish and a bigger push to get the word out to the media.

Jhaveri said he expects the program to reach more consumers this year because of the extra time allotted to the stores and because pharmacists are more aware. He added that he hopes to continue it in future years. “This will be part of our repertoire of raising awareness,” he said.

**Factor X Patch (diclofenac epolamine topical patch) 1.3%**

**Brief Summary:** Rx only

**Cardiovascular Risk:** NSAIDs can cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk (see WARNINGS and Full Prescribing Information). **CLINICAL TRIALS:** Factor X Patch is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see WARNINGS). **Gastrointestinal Risk:** NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events (see WARNINGS).

**INDICATION AND USAGE:** Carefully consider the potential benefits and risks of Factor X Patch and other treatment options before deciding to use Factor X Patch. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (see WARNINGS).

Factor X Patch is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions.

**CONTRAINDICATIONS:** Factor X Patch is contraindicated in patients with known hypersensitivity to diclofenac.

Factor X Patch should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactoid-like reactions to NSAIDs have been reported in such patients (see WARNINGS - Anaphylactoid Reactions, and PRECAUTIONS - Preexisting Asthma).

Factor X Patch is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see WARNINGS).

Factor X Patch should not be applied to non-intact or damaged skin resulting from any etiology e.g. exudative dermatitis, eczema, infected lesion, burns or wounds.

**WARNINGS: CARDIOVASCULAR EFFECTS: Cardiovascular Thrombotic Events:** Clinical trials of several COX-2 selective and nonselective NSAIDs of up to three years duration have shown an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs, both COX-2 selective and nonselective, may have a similar risk. Patients with known CV disease or risk factors for CV disease may be at greater risk. To minimize the potential risk for an adverse CV event in patients treated with an NSAID, the lowest effective dose should be used for the shortest duration possible. Physicians and patients should remain alert for the development of such events, even in the absence of previous CV symptoms. Patients should be informed about the signs and/or symptoms of serious CV events and the steps to take if they occur.

There is no consistent evidence that concurrent use of aspirin mitigates the increased risk of serious CV thrombotic events associated with NSAID use. The concurrent use of aspirin and an NSAID does increase the risk of serious GI events (see GI WARNINGS).

Two large, controlled, clinical trials of a COX-2 selective NSAID for the treatment of pain in the first 10-14 days following CABG surgery found an increased incidence of myocardial infarction and stroke (see CONTRAINDICATIONS).

**Hypertension:** NSAIDs, including Factor X Patch, can lead to onset of new hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of CV events. Patients taking thiazide or loop diuretics may have impaired response to these therapies when taking NSAIDs. NSAIDs, including Factor X Patch, should be used with caution in patients receiving diuretic therapy. Blood pressure (BP) should be monitored closely during the initiation of NSAID treatment and throughout the course of therapy.

**Congestive Heart Failure and Edema:** Fluid retention and edema have been observed in some patients taking Factor X Patch. Factor X Patch should be used with caution in patients with fluid retention or heart failure.

**Gastrointestinal Effects - Risk of Ulceration, Bleeding, and Perforation:** NSAIDs, including Factor X Patch, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the small intestine, or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs. Only one in five patients, who develop a serious upper GI adverse event on NSAID therapy, is symptomatic. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occur in approximately 1% of patients treated for 3-6 months, and in about 2-4% of patients treated for one year. These trends continue with longer duration of use, increasing the likelihood of developing a serious GI event at some time during the course of therapy. However, even short-term therapy is not without risk.

NSAIDs should be prescribed with extreme caution in those with a prior history of ulcer disease or gastrointestinal bleeding. Patients with a prior history of peptic ulcer disease and/or gastrointestinal bleeding, or who are also taking a concurrent increased risk for developing a GI bleed compared to patients with neither of these factors. Other factors that increase the risk of GI bleeding in patients treated with NSAIDs include concomitant use of oral corticosteroids or anticoagulants, longer duration of NSAID therapy, smoking, use of alcohol, concurrent use of aspirin, and poor health status. Most spontaneous reports of fatal GI events are in elderly or debilitated patients and therefore, special care should be taken in treating this population.

To minimize the potential risk for an adverse GI event in patients treated with an NSAID, the lowest effective dose for the shortest possible duration should be used. Patients and physicians should remain alert for signs and symptoms of GI ulceration and bleeding during NSAID therapy and promptly initiate additional evaluation and treatment if a serious GI adverse event is suspected. This should include discontinuation of the NSAID until a serious GI adverse event is ruled out. For high risk patients, alternate therapies that do not involve NSAIDs should be considered.

**Renal Effects:** Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of a nonsteroidal anti-inflammatory drug may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state.

**Advanced Renal Disease:** No information is available from controlled clinical studies regarding the use of Factor X Patch in patients with advanced renal disease. Therefore, treatment with Factor X Patch is not recommended in these patients with advanced renal disease. If Factor X Patch therapy is initiated, close monitoring of the patient's renal function is advised.

**Anaphylactoid Reactions:** As with other NSAIDs, anaphylactoid reactions may occur in patients without known prior exposure to Factor X Patch. Factor X Patch typically should not be given to patients with the aspirin triad. This symptom complex usually occurs in asthmatic patients who experience rhinitis or other upper respiratory symptoms. In some cases, severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs (see CONTRAINDICATIONS and PRECAUTIONS - Preexisting Asthma). Emergency help should be sought in cases where an anaphylactoid reaction occurs.

**Skin Reactions:** NSAIDs, including Factor X Patch, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

**Pregnancy:** In late pregnancy, as with other NSAIDs, Factor X Patch should be avoided because it may cause premature closure of the ductus arteriosus.

**PRECAUTIONS: General:** Factor X Patch cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency. Abrupt discontinuation of corticosteroids may lead to disease exacerbation. Patients on prolonged corticosteroid therapy should have their therapy tapered slowly if a decision is made to discontinue corticosteroids.

The pharmacological activity of Factor X Patch in reducing inflammation may diminish the utility of these diagnostic signs in detecting complications of presumed noninfectious, painful conditions.

**Hepatic Effects:** Borderline elevations of one or more liver tests may occur in up to

15% of patients taking NSAIDs including Factor X Patch. These laboratory abnormalities may progress, may remain unchanged, or may be transient with continuing therapy. Notable elevations of ALT or AST (approximately three or more times the upper limit of normal) have been reported in approximately 1% of patients in clinical trials with NSAIDs. In addition, rare cases of severe hepatic reactions, including jaundice and fatal fulminant hepatitis, liver necrosis and hepatic failure, some of them with fatal outcomes have been reported.

A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of a more severe hepatic reaction while on therapy with Factor X Patch. If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g. eosinophilia, rash, etc.), Factor X Patch should be discontinued.

**Hematological Effects:** Anemia is sometimes seen in patients receiving NSAIDs. This may be due to fluid retention, occult or gross GI blood loss, or an incompletely described effect upon erythropoiesis. Patients on long-term treatment with NSAIDs, including Factor X Patch, should have their hemoglobin or hematocrit checked if they exhibit any signs or symptoms of anemia.

**Aspirin:** When Factor X Patch is administered with aspirin, the binding of diclofenac to protein is reduced, although the clearance of free diclofenac is not altered. The clinical significance of this interaction is not known; however, as with other NSAIDs, concomitant administration of diclofenac and aspirin is not generally recommended because of the potential of increased adverse effects.

**Diuretics:** Clinical studies, as well as post marketing observations, have shown that Factor X Patch may reduce the natriuretic effect of furosemide and thiazides in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis. During concomitant therapy with NSAIDs, the patient should be observed closely for signs of renal failure (see WARNINGS, Renal Effects), as well as to assure diuretic efficacy.

**Lithium:** NSAIDs have produced an elevation of plasma lithium levels and a reduction in renal lithium clearance. The mean minimum lithium concentration increased 15% and the renal clearance was decreased by approximately 20%. These effects have been attributed to inhibition of renal prostaglandin synthesis by the NSAID. Thus, when NSAIDs and lithium are administered concurrently, subjects should be observed carefully for signs of lithium toxicity.

**Methotrexate:** NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. This may indicate that they could enhance the toxicity of methotrexate. Caution should be used when NSAIDs are administered concurrently with methotrexate.

**Warfarin:** The effects of warfarin and NSAIDs on GI bleeding higher than users of other drugs alone.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** **Carcinogenesis:** Long-term studies in rats have not been performed to evaluate the carcinogenic potential of either diclofenac epolamine or Factor X Patch.

**Mutagenesis:** Diclofenac epolamine is not mutagenic in *Salmonella Typhimurium* strains, nor does it induce an increase in metabolic aberrations in cultured human lymphocytes, or the frequency of micronucleated cells in the bone marrow micronucleus test performed in rats.

**Impairment of Fertility:** Male and female Sprague Dawley rats were administered 1, 3, or 6 mg/kg/day diclofenac epolamine via oral gavage (males treated for 60 days prior to coception and during mating period, females treated for 14 days prior to mating through day 19 of gestation). Diclofenac epolamine treatment with 6 mg/kg/day resulted in increased early resorptions and postimplantation losses; however, no effects on the mating and fertility indices were found. The 6 mg/kg/day dose corresponds to 3-times the maximum recommended daily exposure in humans based on a body surface area comparison.

**Pregnancy, Teratogenic Effects, Pregnancy Category C:** Pregnant Sprague Dawley rats were administered 1, 3, or 6 mg/kg diclofenac epolamine via oral gavage daily from gestation days 6-15. Maternal mortality, embryotoxicity, and increased incidence of skeletal anomalies were noted with 6 mg/kg/day diclofenac epolamine, which corresponds to 3-times the maximum recommended daily exposure in humans based on a body surface area comparison. Pregnant New Zealand White rabbits were administered 1, 3, or 6 mg/kg diclofenac epolamine via oral gavage daily from gestation days 6-18. No maternal toxicity was noted; however, embryotoxicity was evident at 6 mg/kg/day group which corresponds to 6.5-times the maximum recommended daily exposure in humans based on a body surface area comparison.

There are no adequate and well-controlled studies in pregnant women. Factor X Patch should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nonsteroidal Anti-inflammatory Drugs (NSAIDs):** Diclofenac epolamine treatment with 6 mg/kg/day group which corresponds to 6.5-times the maximum recommended daily exposure in humans based on a body surface area comparison.

**Nonsteroidal Anti-inflammatory Drugs (NSAIDs):** Diclofenac epolamine treatment with 6 mg/kg/day group which corresponds to 6.5-times the maximum recommended daily exposure in humans based on a body surface area comparison.

**Male rats:** were orally administered diclofenac epolamine (1, 3, 6 mg/kg) for 60 days prior to mating and throughout the mating period, and females were given the same doses 14 days prior to mating and throughout mating, gestation, and lactation. Embryotoxicity was observed at 6 mg/kg diclofenac epolamine (3-times the maximum recommended daily exposure in humans based on a body surface area comparison), and was manifested as an increase in early resorptions, post-implantation losses, and a decrease in live fetuses. The number of live born and total born were also reduced as was F1 postnatal survival, but the physical and behavioral development of surviving F1 pups in all groups was the same as the deionized water control, nor was reproductive performance adversely affected despite a slight treatment-related reduction in body weight.

**Female rats:** were orally administered diclofenac epolamine (1, 3, 6 mg/kg) for 60 days prior to mating and throughout the mating period, and females were given the same doses 14 days prior to mating and throughout mating, gestation, and lactation. Embryotoxicity was observed at 6 mg/kg diclofenac epolamine (3-times the maximum recommended daily exposure in humans based on a body surface area comparison), and was manifested as an increase in early resorptions, post-implantation losses, and a decrease in live fetuses. The number of live born and total born were also reduced as was F1 postnatal survival, but the physical and behavioral development of surviving F1 pups in all groups was the same as the deionized water control, nor was reproductive performance adversely affected despite a slight treatment-related reduction in body weight.

**Labor and Delivery:** In rat studies with NSAIDs, as with other drugs known to inhibit prostaglandin synthesis, an increased incidence of dystocia, delayed parturition, and decreased pup survival occurred. The effects of Factor X Patch on labor and delivery in pregnant women are unknown.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human-milk and because of the potential for serious adverse reactions in nursing infants from Factor X Patch, 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:** Safety and effectiveness in pediatric patients have not been established.

**Geriatric Use:** Clinical studies of Factor X Patch did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. Diclofenac, as with any NSAID, is known to be substantially excreted by the kidney, and the risk of toxic reactions to Factor X Patch may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken when using Factor X Patch in the elderly, and it may be useful to monitor renal function.

**ADVERSE REACTIONS:** In controlled trials during the premarketing development of Factor X Patch, approximately 600 patients with minor strains, sprains, and contusions have been treated with Factor X Patch for up to two weeks.

**Adverse Events Leading to Discontinuation of Treatment:** In the controlled trials, 3% of patients in both the Factor X Patch and placebo patch groups discontinued treatment due to an adverse event. The most common adverse events leading to discontinuation were application site reactions, occurring in 2% of both the Factor X Patch and placebo patch groups. Application site reactions leading to dropout included pruritus, dermatitis, and burning.

**Common Adverse Events: Localized Reactions:** Overall, the most common adverse events associated with Factor X Patch treatment were skin reactions at the site of treatment.

Table 1 lists all adverse events, regardless of causality, occurring in ≥ 1% of patients in controlled trials of Factor X Patch. A majority of patients treated with Factor X Patch had adverse events with a maximum intensity of "mild" or "moderate."

**Table 1. Common Adverse Events (by body system and preferred term) in ≥ 1% of Patients treated with Factor X Patch or Placebo Patch\***

Application Site Conditions	Diclofenac N=572		Placebo N=564	
	N	Percent	N	Percent
Pruritus	64	11	70	12
Dermatitis	21	4	44	8
Burning	9	2	3	<1
Itching	22	4	15	3
<b>Gastrointestinal Disorders</b>	49	9	33	6
Nausea	17	3	11	2
Dyspepsia	16	3	2	<1
Dysphagia	3	0	3	0
Other†	15	3	11	2
<b>Nervous System Disorders</b>	13	2	16	3
Headache	13	2	16	3
Paresthesia	6	1	8	1
Somnolence	4	1	6	1
Other†	1	0	2	<1

\*The table lists adverse events occurring in placebo-treated patients because the placebo patch was comprised of the same ingredients as Factor X Patch except for diclofenac. Adverse events in the placebo group may therefore reflect effects of the non-active ingredients. † Includes: application site dryness, irritation, erythema, alopecia/acoloration, hyperhidrosis, pruritus, itching, burning, stinging, redness, numbness, constriction, upper abdominal pain, and dry mouth. ‡ Includes: hypohesithia, dizziness, and hyperkinesias.

Foreign labeling describes that dermal allergic reactions may occur with Factor X Patch treatment. Additionally, the treated area may become irritated or develop itching, erythema, edema, vesicles, or abnormal sensation.

**DRUG ABUSE AND DEPENDENCE: Controlled Substance Class:** Factor X Patch is not a controlled substance.

**Physical and Psychological Dependence:** Diclofenac, the active ingredient in Factor X Patch, is an NSAID that does not lead to physical or psychological dependence.

**OVERDOSAGE:** There is limited experience with overdose of Factor X Patch. In clinical studies, the maximum single dose administered was one Factor X Patch containing 150 mg of diclofenac epolamine. There were no serious adverse events.

Should systemic side effects occur due to incorrect use or accidental overdose of this product, the general measures recommended for intoxication with non-steroidal anti-inflammatory drugs should be taken.

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