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Moving pharmacy forward: Exhilarating, exhausting

Innovative practice. New pharmacy services. Additional responsibilities. Elevating the status of pharmacists to that of key health care team members. These catchphrases are used frequently at meetings and in journal articles. How many times have you come home from a meeting excited about new opportunities, only to have reality sink in a short while later? Continually moving pharmacy practice forward can cause insomnia.

Innumerable opportunities
It’s not the ideas themselves that keep us awake, but rather that so many opportunities exist! Pharmacists in all realms of practice realize that patients desperately need help with medication management. In the hospital setting, we see patients admitted because they haven’t been taking their medications correctly, and their diseases are out of control. We also see patients admitted after having adverse events from medications. In the community setting, we see patients discharged from the hospital with changes in their medications who are not sure what they should be taking. As patients look for the best economic deal for medications, fragmentation of health care becomes even more prevalent. It’s no longer common to have one pharmacy serve as a patient’s “medication home.” Get a group of pharmacists together in a room and ask for ideas on how to improve the medication use process; we can generate all kinds of ideas and plans to help take care of our patients. The issue is translating those ideas into real, quantifiable measures.

Late-night questions
The problem of implementation keeps many of us up at night, and the barriers can seem overwhelming. How can we convince other pharmacists to move out of their comfort zones to try something new? How can we convince supervisors or hospital administrations that a new project should be funded? Figuring out the logistics of setting up a new program and knowing where to start can be a daunting process. Planning and analysis—skills that many pharmacists possess—can help determine ways of overcoming these barriers.

For years, we have heard that it is time for pharmacists to embrace knowledge rather than product as the cornerstone of patient care. Yes, patients still need to receive drug products; however, pharmacists can provide the best value through information and medication management. Pharmacists must lead the way through medication therapy management services, medication reconciliation programs, and continuity of care, all of which have shown real value. Many pharmacy pioneers have worked through barriers to create excellent programs that have positively affected patients. Patricia Oh, PharmD, our feature profile pharmacist this month, is a shining example of a pharmacist working in one such innovative practice.

There are still plenty of opportunities for pharmacists to provide outstanding patient care. If we allow ourselves to dream and to explore uncharted areas, the possibilities are endless. Many issues keep us awake at night; however, continuing to move pharmacy forward with new approaches to patient care and enhancing the value of the pharmacist may be a good reason to stay awake.

—Melinda C. Joyce, PharmD
Pharmacy Today Health-System Editor

Melinda C. Joyce, PharmD, FAPhA, FACHE, is Corporate Director of Pharmacy at the Medical Center in Bowling Green, KY. She also serves as adjunct faculty for the University of Kentucky College of Pharmacy and Western Kentucky University Department of Nursing. Send your ideas for HSE Insomnia to Dr. Joyce at pt@aphanet.org.
We’ve Always Been STEADY UNDER PRESSURE...

Now We’re READY UNDER PRESSURE
- New Ready-to-Use Bag
- Instant access for rapid intervention
- Eliminates medication admixture errors

2x DOUBLE CONCENTRATION

Important safety information
Close monitoring of the blood pressure is required during therapy. CARDENE I.V. is contraindicated in patients with known hypersensitivity to the drug and in patients with advanced aortic stenosis. Reduction of diastolic pressure and reduced afterload may worsen rather than improve myocardial oxygen balance. Caution is advised when administering CARDENE I.V. to patients with impaired renal or hepatic function, in combination with a beta-blocker in patients with congestive heart failure, or portal hypertension. Observe caution in patients with significant left ventricular dysfunction due to possible negative inotropic effect. CARDENE I.V. gives no protection against the dangers of abrupt beta-blocker withdrawal; beta-blocker dosage should be gradually reduced. Levels of cyclosporine should be closely monitored during therapy. The most common side effects of CARDENE I.V. are headache (14.6%), hypotension (5.6%), nausea/vomiting (4.9%), and tachycardia (3.5%). Less frequent adverse effects, in each case occurring at 1.4%, include ECG abnormalities, postural hypotension, ventricular extrasystoles, injection-site reaction, dizziness, sweating and polyuria.

Please see next page for brief summary of prescribing information.


For more information, visit: www.cardeneiv.com or e-mail us at cardeneiv@ekrtx.com.
CARDENE I.V.
(nicardipine hydrochloride)

Premixed Injection in either 5% Dextrose or 0.83% Sodium Chloride

Brief Summary of Prescribing Information

Cardene I.V. Premixed Injection in 5% Dextrose
40 mg in 200 mL (0.2 mg/mL)
Each mL contains 0.2 mg nicardipine hydrochloride, 50 mg dextrose hydrate, USP, and 0.0384 mg citric acid, anhydrous, USP; Hydrochloric acid and/or sodium hydroxide may have been added to adjust pH to 3.7 to 4.7.

Cardene I.V. Premixed Injection in 0.83% Sodium Chloride
40 mg in 200 mL (0.2 mg/mL)
Each mL contains 0.2 mg nicardipine hydrochloride, 63 mg sodium chloride, USP, 0.0384 mg citric acid, anhydrous USP; and 0.04 mg ascorbic, NF. Hydrochloric acid and/or sodium hydroxide may have been added to adjust pH to 3.7 to 4.7.

INDICATION AND USAGE:
For the short-term treatment of hypertension when oral therapy is not feasible or desirable. For prolonged control of blood pressure, patients should be transferred to oral medication as soon as their clinical condition permits.

CONTRAINDICATIONS:
In patients with known hypersensitivity. Cardene I.V. is also contraindicated in patients who have had angina pectoris because part of the effect of Cardene I.V. is secondary to reduced afterload. Reduction of diastolic pressure in these patients may worsen rather than improve myocardial oxygen balance.

WARNINGS:
BETA-BLOCKER WITHDRAWAL: Nicardipine is not a beta-blocker and provides no protection against the dangers of abrupt beta-blocker withdrawal. Any such withdrawal should be gradual to prevent the risk of rebound hypertension. RAPID DECREASES IN BLOOD PRESSURE: No clinical events have been reported suggestive of a too rapid decrease in blood pressure with Cardene I.V. However, as with any antihypertensive agent, blood pressure lowering should be accomplished over as long a time as is compatible with patient's clinical status.

USE IN PATIENTS WITH CONGESTIVE HEART FAILURE: Use of nicardipine in patients who have had an acute exacerbation of congestive heart failure has been described in less than 1% of CRONARTY disease patients treated with Cardene I.V. Increased frequency, duration, or severity of angina has been with chronic oral Cardene therapy.

USE IN PATIENTS WITH CONGESTIVE HEART FAILURE: Cardene I.V. reduced afterload without impairing myocardial contractility in preliminary hemodynamic studies of OAF patients. However, in vitro and in some patients, a negative inotropic effect has been observed. Exercise caution when using Cardene I.V., particularly in combination with a beta-blocker, in patients with CHF or significant left ventricular dysfunction, in patients with CVC or significant left ventricular dysfunction, in patients with CHF or significant left ventricular dysfunction, or in patients with NYHA class IV heart failure. The following numbers represent the percentage of patients with adverse experiences during the double-blind portion of controlled trials with Cardene I.V. (n=144) versus Placebo (n=100), respectively.

Percent of Patients with Adverse Experiences During the Double-Blind Portion of Controlled Trials

<table>
<thead>
<tr>
<th>Adverse Experience</th>
<th>Cardene I.V. (n=144)</th>
<th>Placebo (n=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body as a Whole</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>14.6</td>
<td>2.0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>14.6</td>
<td>2.0</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>14.6</td>
<td>2.0</td>
</tr>
<tr>
<td>Injection site</td>
<td>14.6</td>
<td>2.0</td>
</tr>
<tr>
<td>Injection site pain</td>
<td>14.6</td>
<td>2.0</td>
</tr>
</tbody>
</table>

Adverse experiences are generally not serious and most were expected effects of vasodilation. Some adverse experiences required dosage adjustments. Therapy was discontinued in about 13% of patients due to hypotension, headache, and tachycardia. The following numbers represent the percentage of patients with adverse experiences during the double-blind portion of controlled trials with Cardene I.V. (n=144) versus Placebo (n=100), respectively.

Adverse Experiences During the Double-Blind Portion of Controlled Trials

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<td>2.0</td>
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</tbody>
</table>

DOSAGE AND ADMINISTRATION: DOSE MUST BE INDIVIDUALIZED depending on severity of hypertension and patient response. Monitor blood pressure during and after the injection; avoid too rapid or excessive reductions in systolic or diastolic blood pressure.

Cardene I.V. premixed injection is available as a single-use, ready-to-use, lecithin-containing solution for Intravenous administration in a 200 mL, GL45 container with 40 mg (0.2 mg/mL) nicardipine hydrochloride in either dextrose or sodium chloride. No further dilution is required. Cardene I.V. premixed injection should not be combined with any product in the same intravenous line or premixed container. Protect from light until ready to use.

See package insert for full prescribing information.

To report an adverse event for questions of a medical nature, please call 1-877-207-5002.

Cardene I.V. is a registered trademark of EK Therapeutics, Inc.

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Bedminster, NJ 07921 USA

Issued December 2008 C08-118
Chronic pain: Which opioid to choose?

Variables affecting opioid therapy discussed

How do you pick an opioid? This was the question that Mary Lynn McPherson, PharmD, Professor in the Department of Pharmacy Practice and Science at the Maryland School of Pharmacy, posed to an overflowing audience at the American Society of Health-System Pharmacists 2008 Midyear Clinical Meeting. McPherson provided a template to be used when navigating the variables affecting therapeutic options for pain management in hospice and end-of-life patients. She stressed that morphine does not always have to be the pharmacist’s first choice when evaluating a patient’s need for chronic pain care. Pharmacists were urged to consider both agent and patient variables.

Dosing appropriately
Dosage formulations are especially critical in end-of-life care situations, McPherson said. She listed the long-acting formulations of opioids currently available, which include long-acting morphine (such as MS Contin—Purdue, Kadian—Actavis, or Avinza—King), oxycodone (OxyContin—Purdue), long-acting tramadol (Ultram ER—Pfizer), long-acting oxymorphone (Opana ER—Endo), and methadone, which is inherently longer acting even without modification of the delivery system, and can be dosed more than once a day. McPherson added that a long-acting transdermal fentanyl patch is also available (Duragesic—Janssen).

Another formulation issue comes up in the question of rescue medication. McPherson said that any time long-acting opioids are used, the caregiver and patient should also have rescue medication on hand. Short-acting morphine and oxycodone tablets and oral solutions are ideal vehicles for rescue medication, as is transmucosal fentanyl, which is available as a lozenge on a stick (Actiq—[McNeil]).” Extending the dosing interval breaks the cycle of pain, analgesia, confusion, and sedation.

Pharmacokinetics
All opioids are metabolized extensively by the liver, and pharmacists should be concerned about those patients who have active metabolites, McPherson said. Even morphine has many active metabolites, such as the M3 and M6 glucuronides, that can cause persistent nausea, hallucinations, and myoclonus. Oxycodone and hydromorphone, McPherson posited, probably have less activity in their metabolites. Fentanyl and methadone have negligible metabolite activity, making them the best choice for patients with end-stage renal disease.

Adverse effects and toxicities
Constipation is a class-wide adverse effect of opioids, which cause peristalsis within minutes of administration. Nausea, vomiting, sedation, itching, respiratory depression, and confusion are also common adverse effects. Patients can develop a tolerance to some of these effects (nausea, sedation, confusion) while others such as itching—likely caused by histamine release—and constipation remain problematic. Some tolerance to respiratory depression can also be achieved after several days to a week of therapy. Codeine’s adverse effects, particularly nausea, are dose limiting in nature.

Patient variables
In choosing a course of treatment for a patient suffering from chronic pain, pharmacists are urged to take into account the kidney and liver function of the patient, whether patients will be adherent to therapy, other diseases present, available support systems, whether patients are able to manage their medications, and patients’ manual dexterity where transdermal application is needed.

—Beth Farnstrom
Bringing MTM to wounded warriors

Patricia Oh works with patients at Walter Reed Army Medical Center

Patricia Oh, PharmD, thinks she works in the ideal pharmacy practice setting. Oh is a Clinical Pharmacist in the Warrior Clinic at Walter Reed Army Medical Center (WRAMC) in Washington, DC, which serves an average of 700 soldiers in transition under its care at any one time. Oh recently told Pharmacy Today, “I’m really privileged to be here and to serve my profession in this way.” The Warrior Clinic was developed to serve wounded soldiers and their families with an integrated primary care team. She has been with the clinic since it opened on a full-time basis in October 2007.

Drawn to ambulatory care
Oh was born in Seoul, South Korea, and immigrated to the United States with her family when she was 5 years old. She sees her interest in pharmacy as a natural progression from her undergraduate degree in biology. She knew she wanted to work in the health field because, as she told Today, “As a reflection of my upbringing and my faith as a Christian, I had a heart for helping people but at the same time. I enjoyed learning about medications, mechanisms, and the science behind how things work and how they affect our bodies.”

In 2002, Oh received her PharmD from the Medical College of Virginia (MCV) at Virginia Commonwealth University School of Pharmacy, and she stayed on in Richmond to complete a 2-year residency in pharmacy practice, specializing in ambulatory care. During her time there, she encountered several great mentors and preceptors in the field. She said, “I had the great experience of meeting patients one on one and shaping their medication therapy based on the recommendations I made to the physicians.” The residency experience confirmed her passion for ambulatory care and, ultimately, led her to take the position of Clinical Pharmacist at WRAMC when she finished her residency in 2004. Oh explained, “I knew that WRAMC had a wide variety of ambulatory care experiences and it would be a great place for professional development and growth.”

Starting from scratch
Oh worked in the Geriatrics and Internal Medicine Clinics at WRAMC before joining the medical center’s fledgling Warrior Clinic. Because the Warrior Clinic was brand new, Oh had the responsibility of developing her own position—deciding what services she would provide, writing her own standards of practice, and even setting up her own appointment templates. She had to figure out how to integrate a warfarin management clinic under the cardiology service while maintaining her identity and role as part of the Warrior Clinic. Oh worked through these challenges by drawing on her previous experiences in internal medicine clinics as well as advice from peers and others at WRAMC who had themselves started existing clinics.

The Warrior Clinic aims to provide coordination, continuity, and a holistic approach to care for wounded soldiers and their families. Its structure is based on the Army’s Triad of Care model, which assigns each soldier a primary care manager, a nurse case manager, and a squad leader. The primary care and nurse case managers coordinate the patient’s medical care, while the squad leader ensures that the soldier’s military and nonmedical needs are met; in addition to serving as a mentor, the squad leader sees that the soldier’s promotions are on track and pay is correct. Oh works closely with both the primary care and nurse case managers and sees her own mission as one of supporting the Triad of Care for her patients.

Not your average cases
Oh’s patient population is unique, and her patients usually come to her after a lengthy hospital stay. She sees many patients with traumatic brain injury, posttraumatic stress disorder (PTSD), depression, and amputations. Pain management is a large part of her practice, although she also works to manage and educate her patients with chronic diseases such as hyperlipidemia and diabetes. She refers patients to WRAMC wellness services for such needs as nutrition education and smoking cessation when she sees a need.

Oh sees 6 to 10 patients per day by appointment but is also available for phone consults. Initial MTM appointments are 45 to 60 minutes, and follow-up and noncomplex appointments are 30 minutes. During these one-on-one sessions, Oh reviews patients’ medications and disease management and assesses therapy goals as established by national guidelines. If the patient is not at goal, she makes appropriate recommendations to discontinue, initiate, or adjust patients’ medication dosages. MTM is provided to soldiers as part of their active duty military service benefits.

Oh sees her position as an ideal situation in which to practice MTM because the physicians are open to a multidisciplinary approach to patient care and value pharmacy recommendations in medication management. In addition, in the Warrior Clinic, the providers are physically right down the hall from her.
many faces of MTM
office. “If a patient’s blood pressure is uncontrolled and I want to increase a blood pressure medication, they’re usually very supportive,” she said. That communication goes both ways—physicians will often stop by to ask her questions and obtain specific drug information. Oh explained that at WRAMC, pharmacists are considered credentialed providers, so they have the autonomy to adjust meds while working with the primary care provider; for example, she self-adjusts warfarin medication for most of her patients. “The patients actually view my visits as an integral part of their care,” she explained.

Oh’s regular patients know that every time they see their primary care physician and have their specialty visits, they need to come back and see her. She told Today, “The physicians make referrals in their notes to see Dr. Oh for pharmacy review and medication management.”

**Preceptor and researcher**

Oh serves as preceptor in the department of pharmacy for residents and student pharmacists doing ambulatory care rotations at WRAMC. The pharmacy residents and students spend time in the Warrior Clinic as well as the HIV, geriatrics, internal medicine, and other clinics at WRAMC.

As part of her role at WRAMC, Oh is also expected to participate in research when possible. She and other pharmacists at WRAMC helped collect data for FAME (Federal Study of Adherence to Medications in the Elderly), a randomized controlled trial published in the *Journal of the American Medical Association*. For FAME, Jeannie Lee, PharmD, and Karen Grace, PharmD, both clinical pharmacists at WRAMC, along with Allen Taylor, MD, tested the efficacy of a comprehensive pharmacy care program designed to improve medication adherence and its associated effects on blood pressure and LDL cholesterol. A total of 200 patients were enrolled in a 6-month intervention for the study. Patients met with clinical pharmacists to learn drug names, strengths, adverse effects, and usage instructions of their medications. After 6 months of intervention, 97% of patients were adherent to their treatment and clinically significant improvements in blood pressure were seen.

Oh has served on committees specific to the Warrior in Transition. She participated in a Department of Defense–wide, multidisciplinary Comprehensive Transition Plan Workshop to establish best practices of care for patients beginning with pre-entry through post-transition. She also serves as a pharmacy representative to a Warrior in Transition Working Group to help address pertinent medication-related issues, such as medication reconciliation and safety.

As a result of her work at the Warrior Clinic, Oh was awarded the 2008 Mel Liter Army Clinical Pharmacist of the Year and the Commander’s Award for Civilian Service for Pharmacy Services. She also was accepted for a 2-week pain management training program in Baltimore sponsored by the American Society for Health-System Pharmacists. Her training has helped improve patient and provider education in pain management and establish clinic policies related to pain management and medication safety.

**More than a sum of the parts**

In the end, Oh’s role is much more than medication review or patient education. She said, “It’s not just the medication management, but it has been about the relationships I’ve been able to build with these patients while witnessing their recovery process. It’s amazing to see their strength and to be a part of their whole healing—not just the physical but spiritual and emotional healing. These are the things that really touch my heart and make my job worthwhile.”

–Carli Richard
MINIMICROSPHERES® (Pancrelipase Delayed-release Capsules, USP)

DOSAGE AND ADMINISTRATION

Adults and Children Over 6 Years Old

Clinical experience should dictate initial starting dose. Doses should be taken during meals or in between meals. When changing strengths of pancreatic enzyme products, care should be taken to maintain equivalent USP units for each divided dosage. It is important to ensure adequate hydration of patients at all times while taking pancreatic enzymes.

Where swallowing of capsules is difficult, the capsules may be carefully opened and the content emptied into fruit juice immediately without chewing and followed with a glass of water or juice to insure swallowing.

HOEPEX 10 capsules are available in a two-piece gelatin capsule (brown opaque top half, blue opaque bottom half) imprinted in white with "SOLVAY" and "1010". Each capsule contains tan-colored delayed-release MINIMICROSPHERES® of pancrelipase supplied in bottles of:

- 100 NDC: 0032-1210-01
- 250 NDC: 0032-1207-07

CREON® 5 capsules are orally administered and contain pancrelipase (ipase, 5,000 USP Units, porcine pancreatic origin, and amylose, 16,650 USP Units per capsule) which is of porcine pancreatic origin. Each CREON 5 Capsule is filled with 124 mg of delayed-release MINIMICROSPHERES®. Inactive ingredients include dibutyl phthalate, dimethicone, hydroxypropylmethylcellulose phthalate, light mineral oil and polyethylene glycol. The capsule shells contain gelatin, red iron oxide, titanium dioxide, FD & C Blue No. 2. The capsule imprinting ink contains dimethicone, 2-ethoxyethanol, shellac, soya lecithin, and titanium dioxide.

CLINICAL PHARMACOLOGY

The pancreatic enzymes in CREON 5 Capsules are enterico-coated to resist gastric destruction or inactivation. The pancreatic enzymes catalyze the hydrolysis of fats to glycerol and fatty acids, protein into proteoses and derived substances and starch into dextrins and short chain sugars.

INDICATIONS

CREON 5 Capsules are indicated for patients with pancreatic exocrine insufficiency as is often associated with:
- cystic fibrosis
- chronic pancreatitis
- post-pancreatectomy
- post-gastrointestinal bypass surgery (e.g., Billroth II gastroenterostomy)
- ductal obstruction from neoplasm (e.g., of the pancreas or common bile duct)

CONTRAINDICATIONS

CREON 5 Capsules are contraindicated in the early stages of acute pancreatitis or in patients who are known to be hypersensitive to pork protein.

WARNINGS

Should symptoms of hypersensitivity appear, discontinue medication and initiate symptomatic and supportive therapy if necessary. Structures in the ileo-cecal region and/or ascending colon have been reported in cystic fibrosis patients treated with high doses of high-potency pancreatic enzyme supplements containing 20,000 or greater USP units of lipase per capsule. The underlying mechanism is unknown, but caution should be exercised when doses in excess of 6,000 USP units lipase per kg per meal fail to resolve symptoms, especially in patients with a history of intestinal complications such as mechanical or less extensive ischemic syndromes. If an asymptomatic patient ingesting high doses of pancreatic enzymes in enteric-coated capsules begins to experience suggestive of gastrointestinal obstruction occur, the possibility of bowel stricture should be investigated including evaluation with an upper gastrointestinal endoscopy.

PRECAUTIONS

CREON 5 capsules MINIMICROSPHERES SHOULD NOT BE CRUSHED OR CHEWED or placed on foods having a pH greater than 5.5. These can dissolve the protective enteric coating resulting in early release of enzymes, irritation of oral mucosa, and/or loss of enzyme activity. Information for Patients

CREON 5 Capsules are a pancreatic enzyme product prescribed to promote improved digestion of food by providing supplemental enzyme content. The prescribed dose range should not be exceeded without calling your doctor.

The most common adverse reactions involve the stomach and intestine including diarrhea, nausea, vomiting, bloating, constipation, stomach cramps or pain. If these symptoms are persistent, contact your doctor.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy, Category C

Pregnancy has not been investigated including evaluation of pancreatic enzyme therapy.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CREON 5 Capsules are administered to a nursing mother.

ADVERSE REACTIONS

The most frequently reported adverse reactions to pancreatic enzyme-containing products are gastrointestinal in nature which may include nausea, vomiting, bloating, cramping, constipation or diarrhea. Less frequently, allergic-type reactions have also been observed. Very high doses of pancreatic enzymes have been associated with hyperuricosuria and hyperuricemia.

DOSAGE AND ADMINISTRATION

Clinical experience should dictate initial starting dose. Doses should be taken during meals or snacks, not before or after. Do not take without food.

Adults and Children Over 6 Years Old

Usual initial starting dose is one to four CREON 5 Capsules per meal or snack.

Children Under 6 Years Old

The exact dosage of CREON 5 Capsules should be selected based on clinical experience for this age group. Patients can be started on one to two capsules per meal or snack.

For cystic fibrosis patients, typical doses are 1,500 - 3,000 USP lipase units/kg/meal. Dosage should be adjusted according to the severity of the disease, control of steatorrhea and maintenance of good nutritional status. Doses in excess of 6,000 USP units lipase/kg/meal are not recommended.

Dose increases, if required, should occur with careful monitoring of body weight and stool fat content. When changing strengths of pancreatic enzyme products, care should be taken to maintain equivalent USP units for each divided dosage. It is important to ensure adequate hydration of patients at all times while taking pancreatic enzymes.

Where swallowing of capsules is difficult, the capsules may be carefully opened and the MINIMICROSPHERES added to a small amount of soft food, with a pH less than 5.5. The soft food should be swallowed immediately without chewing and followed with a glass of water or juice to insure swallowing.

HOEPEX 10 capsules are available in a two-piece gelatin capsule (orange opaque top half, blue opaque bottom half) imprinted in white with "SOLVAY" and "1010". Each capsule contains tan-colored delayed-release MINIMICROSPHERES® of pancrelipase supplied in bottles of:

- 100 NDC: 0032-1210-01
- 250 NDC: 0032-1207-07

CREON 5 Capsules must be stored at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature Use] PROTECT FROM MOISTURE. DO NOT REFRIGERATE. Disperse in tight, light-resistant containers. For human consumption only. Manufactured by:

Solvay Pharmaceuticals, Inc.

Marketed by:

Solvay Pharmaceuticals, Inc.

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MINIMICROSPHERES® (Pancrelipase Delayed-release Capsules, USP)

DOSAGE AND ADMINISTRATION

Adults and Children Over 6 Years Old

Dosage increases, if required, should occur with careful monitoring of body weight and stool fat content. When changing strengths of pancreatic enzyme products, care should be taken to maintain equivalent USP units for each divided dosage.

Where swallowing of capsules is difficult, the capsules may be carefully opened and the MINIMICROSPHERES added to a small amount of soft food, with a pH less than 5.5. The soft food should be swallowed immediately without chewing and followed with a glass of water or juice to insure swallowing.

HOW SUPPLIED

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- 100 NDC: 0032-1210-01
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YOU’LL BE HAPPY TO KNOW CREON® IS STILL THERE FOR YOU.

INDICATION
CREON® is indicated for patients with pancreatic exocrine insufficiency as is often associated with cystic fibrosis, chronic pancreatitis, post-pancreatectomy, post-gastrointestinal bypass surgery, and ductal obstruction from neoplasm.

IMPORTANT SAFETY INFORMATION
• Contraindications: CREON® is contraindicated in the early stages of acute pancreatitis or in patients who are known to be hypersensitive to pork protein.
• Warnings: Should symptoms of hypersensitivity appear, discontinue medication and initiate symptomatic and supportive therapy if necessary.
• Adverse Reactions: The most frequently reported adverse reactions to pancreatic enzyme-containing products are gastrointestinal in nature which may include nausea, vomiting, bloating, cramping, constipation or diarrhea. Less frequently, allergic-type reactions have also been observed. Very high doses of pancreatin have been associated with hyperuricosuria and hyperuricemia.

CREON is a registered trademark of Solvay Pharmaceuticals, Inc.
Please see full Prescribing Information on the previous pages.

CREON® didn’t become the #1-prescribed pancreatic enzyme brand overnight.¹
We’ve had over 20 years of success helping patients lead healthier lives.

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