Methylnaltrexone (Relistor) For Opioid-Induced Constipation

The U.S. Food and Drug Administration (FDA) has approved methylnaltrexone bromide (Relistor, Wyeth, Progenics) to help restore bowel function in patients with late-stage, advanced illness who are receiving opioids on a continuous basis to alleviate pain. Opioids can interfere with normal bowel elimination by relaxing the intestinal smooth muscles and preventing them from contracting. Relistor blocks opioid entrance into the cells and enables the bowels to continue to function normally.

An injectable medication, Relistor can be administered as needed, but only one dose should be given in a 24-hour period. The recommended starting schedule is one dose every other day as needed.

Relistor is not recommended for those patients with intestinal obstruction. Patients experiencing severe diarrhea, vomiting, nausea, or abdominal pain during therapy should stop taking this medication and should consult with their health care providers.

(Source: FDA, April 28, 2008.)

Generic Requip (Ropinirole)

The first generic versions of GlaxoSmithKline’s Requip (ropinirole HCl) tablets have been approved for the treatment of moderate to severe restless legs syndrome in dosages strengths of 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg. Roxane, Teva, Par, and Mylan have received approval to market the tablets.

The labeling for the generic versions may differ from that of Requip, because some uses are protected by patents. Requip is also approved to treat symptoms of Parkinson’s disease (PD). The generic product was scheduled to be eligible for treating PD after late May.

The generic tablets will carry the same safety warnings as Requip, such as cautions about falling asleep while engaged in activities of daily living and driving.

(Source: FDA, May 9, 2008.)

Once-Daily Taclonex For Scalp Psoriasis

Warner Chilcott and LEO Pharma have announced the FDA’s approval of their New Drug Application (NDA) for calcipotriene 0.005%/betamethasone dipropionate 0.064% (Taclonex Scalp Topical Suspension) for the topical treatment of moderate to severe psoriasis vulgaris of the scalp in adults. Known as Xamiol outside the U.S., it is scheduled to be launched in the second half of 2008.

(Source: Warner Chilcott/LEO, May 12, 2008.)

Phentolamine (OraVerse) After Dental Anesthesia

The FDA has approved phentolamine mesylate (OraVerse, Novalar) for the reversal of soft-tissue anesthesia and the associated deficits resulting from local anesthetics used by dentists. This is the only local anesthetic-reversal agent that accelerates the return to normal sensation and function after restorative and periodontal procedures. Phentolamine has also been used to treat hypertension.

Lidocaine is usually combined with epinephrine to constrict the blood vessels. OraVerse dilates the blood vessels and speeds up blood flow so that the anesthetic can be carried away; the injection reverses epinephrine, not lidocaine or the anesthetic.

Local dental anesthetics frequently result in unnecessary and lingering numbness. OraVerse reverses numbness of the lip and tongue and deficits resulting from an intraoral submucosal injection of a local anesthetic containing a vasoconstrictor.

In clinical studies, OraVerse reduced the median time needed for recovery of normal sensation in the lower and upper lip. Within one hour, 41% of the patients reported normal lower-lip sensation, compared with 7% of controls, and 59% of the patients reported normal upper lip sensation, compared with 12% of controls. No serious events were reported except temporary injection-site pain.

OraVerse is not intended for children younger than six years of age, children who weigh less than 33 pounds (15 kg), or patients undergoing root canals or tooth extractions.

Novalar plans to launch OraVerse at this year’s American Dental Association meeting in October 2008.

(Source: FDA; The New York Times, May 12, 2008.)

Alvimopan (Entereg) For Postoperative Ileus

The FDA has approved alvimopan (Entereg, Adolor/GlaxoSmithKline) to accelerate the restoration of bowel function in patients 18 years of age and older after partial large-bowel or small-bowel surgery. Alvimopan is indicated for hospitalized patients who can receive no more than 15 doses.

The FDA is approving alvimopan with a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the drug’s benefits outweigh its risks. The product is restricted to inpatient use only.

After abdominal surgery, patients may experience temporary impairment of gastrointestinal (GI) tract motility. Some pain relievers, such as morphine, can slow or inhibit normal motility. Alvimopan blocks opioid effects in the bowel.

The recommended dose is one 12-mg capsule given just before surgery and another 12-mg dose twice daily for up to seven days, not to exceed 15 doses. The product is not approved for use in children.

(Source: FDA, May 20, 2008.)
NEW INDICATIONS

Fluticasone/Salmeterol (Advair) For COPD Exacerbations

A combination of fluticasone propionate 250 mcg and salmeterol 50 mcg inhalation powder (Advair Diskus, GlaxoSmithKline 250/50) has been approved for reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD), the fourth leading cause of death in the U.S.

Patients who are experiencing worsening COPD symptoms often require additional treatment, such as antibiotics, oral corticosteroids, and sometimes hospitalization. Symptoms include coughing, shortness of breath, or coughing up excess mucus beyond normal variations.

The FDA also expanded the use of Advair Diskus 250/50 to include COPD associated with chronic bronchitis as well as with emphysema or both. Advair 250/50 was originally approved in 2003 for the maintenance treatment of airflow obstruction in patients with COPD associated with chronic bronchitis.

Patients should take only one inhalation twice a day. Advair should not be used with long-acting beta2-agonists, and it should not be used to treat sudden symptoms.

(Source: GlaxoSmithKline, May 1, 2008.)

Bipolar Indication, New Dose For Aripiprazole (Abilify)

Bristol-Myers Squibb and Otsuka have announced updated labeling for aripiprazole (Abilify) as an adjunctive therapy to either lithium or valproate for the acute treatment of manic and mixed episodes associated with bipolar I disorder with or without psychotic features in patients 10 to 17 years of age. The injection form is indicated for the acute treatment of agitation associated with bipolar I disorder, manic or mixed, in adults. The FDA also approved a new recommended starting and target dose of 15 mg daily for aripiprazole alone in treating bipolar I disorder in adults.

(ASources: Bristol-Myers Squibb/Otsuka, May 8, 2008.)

Atomoxetine (Strattera) For ADHD Maintenance In Children and Adolescents

Atomoxetine HCI (Strattera, Eli Lilly) has been approved for the maintenance treatment of attention-deficit/hyperactivity disorder (ADHD) in children and adolescents. This selective norepinephrine reuptake inhibitor is the first FDA-approved nonstimulant indicated for treating ADHD in children, adolescents, and adults.

In an 18-month, relapse-prevention trial of 600 children and adolescents six to 15 years of age, atomoxetine was superior to placebo in maintaining continuous efficacy in patients. At the end of the trial, patients taking the study drug had lower relapse rates (2.5%), compared with patients taking placebo (12.2%). The mean final dose was approximately 1.54 mg/kg per day after 12 months and 18 months of treatment.

In some children and teenagers, atomoxetine increased the risk of suicidal thoughts, but a similar analysis in treated adults did not reveal this risk.

Atomoxetine is not indicated for those patients who have taken a monoamine oxidase inhibitor antidepressant within the previous two weeks; who have glaucoma; or who are allergic to any of the drug’s ingredients.

(Sources: Eli Lilly, May 8, 2008; www.strattera.com.)

Lubiprostone (Amitiza) For Irritable Bowel Syndrome With Constipation

The FDA has approved lubiprostone (Amitiza, Sucampo/Takeda) to treat irritable bowel syndrome with constipation (IBS-C) in women 18 years of age and older. IBS affects at least twice as many women as men.

The safety and efficacy of lubiprostone were established in two major studies involving 1,154 patients with IBS-C. About 92% of the patients were women. More treated patients reported symptom relief over a 12-week period compared with patients who received placebo.

The medication is also approved for patients with chronic idiopathic constipation. Lubiprostone is discussed in this month's Pharmaceutical Approval Update on page 362.

(Source: FDA, April 30, 2008.)

NEW FORMULATIONS

Delivery System (Mixject) For Testosterone Inhibitor (Trelstar) in Prostate Cancer

Watson Pharmaceuticals, Inc., has announced the FDA’s approval of Mixject, a delivery system for triptorelin pamoate (Trelstar), an injectable suspension for the palliative treatment of advanced prostate cancer. Developed by Medimop (a subsidiary of West Pharmaceutical Services), Mixject combines the efficacy of Trelstar Depot 3.75 mg and long-acting (LA) Trelstar 11.25 mg.

Trelstar is a synthetic luteinizing hormone–releasing hormone (LHRH) ago-
nist that suppresses testosterone production and reduces prostate-specific antigen (PSA) levels. The growth of the prostate gland is regulated in part by testosterone levels.

New features include a smaller 21-gauge needle for improved patient comfort, reconstitution without the use of a needle, and a shield that covers the needle before and after the drug is given.

Trelstar is available in a four-week depot form and a 12-week long-acting form. It should be stored at room temperature. Trelstar may initially cause a temporary increase in testosterone levels, and symptoms may worsen during this period. Cases of anaphylactic shock and angioedema have been reported.

Approved in 2001, Trelstar was developed by Debiopharm and was also indicated for endometriosis in women.

(Source: Watson, April 30, 2008.)

**Factor VIIa (NovoSeven RT) Coagulation Therapy**

The FDA has approved a new formulation of the genetically engineered version of factor VIIa (NovoSeven RT, Novo Nordisk), a plasma protein essential for the clotting of blood. NovoSeven RT can be stored at room temperature (up to 77° F) for up to two years, an advantage for health care facilities with limited refrigeration space. The original formula could be stored for three years at temperatures between 36° and 46° F.

(Source: FDA, May 8, 2008.)

**NEW DOSAGE**

**Once-Monthly Risedronate (Actonel) for Osteoporosis**

The FDA has approved Procter & Gamble’s new once-a-month dose (150 mg) of risedronate sodium (Actonel) tablets for the treatment and prevention of postmenopausal osteoporosis. This approval was based on a study comparing the 150-mg once-monthly dose with the 5-mg daily dose. Similar increases in bone mineral density were seen among patients taking either regimen.

(Source: FDA, April 24, 2008; www.actonel.com.)

**DRUG NEWS**

**Digoxin Tablets Recalled**

Actavis Totowa LLC (formerly Amide) is initiating a Class I nationwide recall of all strengths of oral digoxin tablets, USP (Digitek). Mylan distributes the products under a Bertek label, and UDL Laboratories, Inc., distributes them under a UDL label.

It is possible that tablets with twice the appropriate thickness might have been released.

Digitek is used to treat heart failure and arrhythmia. A double-strength tablet poses a risk of digitalis toxicity in patients with renal failure. Retailers should return the product to their place of purchase, and consumers should contact their health care providers.

(Source: FDA, April 25, 2008; www.activis.us.)

**Treating Trichomonas Infection**

Approximately 3% of women have *Trichomonas vaginalis*, the most common nonviral sexually transmitted disease in the U.S. Two chemically similar drugs are recommended for treating this infection: metronidazole (Flagyl, Pfizer) and tinidazole (Tindamax, Mission Pharmacal). However, if the patient is hypersensitive to either or both drugs, alternatives are few. One answer might be incremental dosing, or desensitization, of oral and IV metronidazole.

Researchers from the Centers for Disease Control and Prevention (CDC) analyzed data from 59 infected women who had reactions such as urticaria and facial edema when they received metronidazole. Fifteen women were treated with metronidazole desensitization, and the infection was eradicated in all 15. When 17 patients were given other intravaginal medications, such as a Betadine (Purdue) douche and clotrimazole (Lotrimin, Schering), the infection was eradicated in only five women. Eighteen women were not treated.

Few adverse effects were noted. One woman who received oral metronidazole desensitization developed a pruritic rash on the final day. Another who received IV metronidazole desensitization experienced mild urticaria and pruritus 45 minutes after the final 2-g dose, and she was managed with diphenhydramine (Benadryl, McNeil/Johnson & Johnson).

(Source: *Am J Obstet Gynecol* 2008;198:370e1–370e7.)

**Drug-Eluting Stents Benefit the Elderly**

Although octogenarians are considered to be at high risk for many operative procedures, drug-eluting stent implantation shouldn’t be one of them, say Mayo Clinic researchers. In a study of 2,453 patients, the stents were successful 98% of the time in subjects older than 80 years of age, even with their higher prevalence of comorbidities and multivessel disease. During the 12 months after discharge, mortality rates were higher in the octogenarians (9% vs. 3% in younger patients) and occurred more often from cardiac causes—but life expectancy was similar to that of the general population. There was no significant difference in 12-month target lesion revascularization or coronary artery bypass grafting.

(Source: *Am Heart J* 2008;155:680–686.)

... But Thrombosis Occurred in Another Stent Study

Rates of late thrombosis, a concern with drug-eluting stents, have been variously reported at less than 1% and at more than 2%. Researchers from Spain...
suggest the real-world rate might be closer to 3%. In their study, which included a long follow-up period (median, 34 months), most cases of delayed thrombosis occurred very late.

During follow-up, thrombosis developed in 17 of 604 patients. Nearly all 14 events took place more than one year after the stent was placed (median, 19 months). All patients who developed late definite thrombosis experienced ST-elevation myocardial infarction (MI), and four patients died. Thrombosis was independently related to a higher risk of all-cause death, cardiac death, nonfatal MI, and further revascularization.

(Source: *Am Heart J* 2008;155:648–653.)

**Venlafaxine ER (Effexor) In Late-Life Depression**

Health care providers might consider Wyeth’s venlafaxine extended-release (Effexor) as a first-choice drug for late-life depression, say researchers from Madrid, Spain. Their study of 59 patients found response rates of 82% and remission rates of 60% by week 24. Only 7% of patients reported adverse drug events throughout the study; all events were mild to moderate. Although no significant effects were observed on blood pressure or heart rate, the researchers caution that the sample size was small. Nevertheless, they add, their data are reinforced by other data from double-blind or single-blind studies.

(Source: *Arch Gerontol Geriatr* 2008;46:317–326.)

**For Best Results, Reduce Blood Pressure And LDL-Cholesterol Even More**

Aggressively lowering targets for low-density lipoprotein-cholesterol (LDL-C) and blood pressure (BP) produced impressive results for 499 American Indian adults with diabetes, say researchers in the Stop Atherosclerosis in Native Diabetics Study (SANDS) randomized trial.

Researchers assigned patients to receive aggressive therapy (with a goal of 70 mg/dL or less for LDL-C and 115 mm Hg or less for systolic BP) or to standard therapy (with a goal of 100 mg/dL or less and 130 mm Hg or below).

After 36 months, mean carotid intimal media thickness progressed slightly with standard treatment and regressed with aggressive therapy. At 36 months, there was a significant difference between the two groups, and plaque scores increased slightly in both groups. Left ventricular mass and left ventricular mass index decreased slightly in both groups of patients but to a greater degree with intensive therapy. Rates of adverse events were low in both groups; eight participants died.
Although the total number of primary or secondary cardiovascular disease endpoints did not differ significantly between the two groups, targeted treatment of LDL-C and systolic BP seemed to bring about improvements, with greater benefits attributable to the lower target levels.

(Source: JAMA 2008;299:1678–1689.)

Can Surgery Correct Diabetes?

New evidence points to the role of the small bowel in diabetes development. Simply restricting the stomach’s size by gastric banding improves diabetes only by inducing massive weight loss. In animal studies, gastric bypass involving rerouting of the GI tract causes diabetes remission independently of weight loss, even in non-obese subjects.

The GI tract plays an important role in energy regulation, and GI hormones are involved in sugar metabolism. When the passage of nutrients is diverted from the upper intestine of diabetic patients, diabetes seems to resolve. The study author (Dr. Rubino) proposed an explanation known as the “anti-incretin theory.”

Incretins (GI hormones) are produced in response to the transit of nutrients that boost insulin production. Because an excess of insulin can determine hypoglycemia, Dr. Rubino speculated that a counterregulatory (anti-incretin) mechanism is activated by the same passage of nutrients through the upper intestine. The latter mechanism would act to decrease both the secretion and the action of insulin.

With type-2 diabetes, cells are resistant to the action of insulin, and the pancreas does not produce enough insulin to overcome the resistance. After GI bypass, exclusion of the upper small intestine from the transit of nutrients may offset the abnormal production of anti-incretin, thereby resulting in remission of diabetes. Bariatric surgery is usually recommended only in cases of severe obesity, but Dr. Rubino says that surgery might also help patients who are only slightly obese or just overweight.

(Source: Science Daily, March 6, 2008; Diabetes Care, February 2008.)

Fluvastatin (Lescol)

For Cholesterol: Fewer Muscle Effects?

About 5% to 10% of patients who use statins to lower cholesterol experience muscle-related side effects, sometimes severe enough to warrant stopping treatment. For those patients, an extended-release form of fluvastatin (Lescol, Novartis) may offer a solution.

Researchers assessed the efficacy and tolerability of fluvastatin XL and ezetimibe (Zetia, Merck/Schering-Plough) alone or in combination. They chose ezetimibe as the only well-tolerated cholesterol drug with a reported placebo-like adverse-event profile.

In a double-blinded trial of 199 patients with mostly moderate-risk or high-risk dyslipidemia, fluvastatin XL lowered LDL-C levels by 33%; ezetimibe lowered them by 16%; and the combination lowered them by 46%. Of the patients receiving ezetimibe, 24% had muscle-related side effects, compared with 17% in the fluvastatin group and 14% in the combination group.

No instances of rhabdomyolysis or creatine kinase increases more than 10 times the upper limit of normal were noted. The researchers suggested that tolerability was a result of fluvastatin’s unique pharmacokinetic properties. The slow release of fluvastatin XL from the GI tract increases first-pass hepatic uptake, avoiding hepatic saturation and thus reducing peripheral blood drug concentrations. The low lipophilicity of fluvastatin might have also contributed to slower passage into the muscle cells.

(Source: Am J Cardiol 2008;101:490–496.)

Quicker Titration Of Galantamine (Razadyne) In Alzheimer’s Disease

For patients with Alzheimer’s disease, acetylcholinesterase inhibitors are usually titrated in four-week intervals, primarily because of their GI side effects. Researchers from Ohio State University, however, say that changing to a one-week titration of extended-release galantamine (Razadyne ER, Ortho-McNeil) is safe and might allow a maintenance dose to be established sooner.

In a 12-week, open-label study, extended-release galantamine was titrated from 8 to 16 mg/day after one week. The results through weeks 8 and 12 were compared with safety and tolerability data for extended-release and immediate-release galantamine from a previous six-month randomized trial. Overall, the one-week titration was well tolerated. Of the 83 patients enrolled, 66 completed the 12-week study. Nine patients stopped therapy because of adverse events. At 12 weeks, no statistically significant differences were observed between treatment groups in terms of GI adverse events.

Although the most frequent adverse event in the one-week titration study was diarrhea, 11% of the patients in the one-week titration study and 1.3% of those in the four-week titration study already had diarrhea at the baseline examination. A consistent temporary relationship between onset of incident diarrhea and dose titration was not observed in either study, suggesting that the titration schedule itself did not increase the risk of diarrhea. Moreover, any diarrhea occurring after the baseline examination was typically mild and was not associated with early discontinuation.

Theoretically, a one-week titration schedule could permit dosing flexibility. In this study, mean Mini-Mental State Examination scores improved by 1.8 points at the fourth week and by 1.9
points at the 12th week. If earlier titration results in earlier cognitive effects, adherence to medication might also improve. (Source: *Alzheimer Dementia* 2008;4:430–437.)

**New Latex Glove**

The FDA has approved a new form of natural rubber latex (guayule, Yulex). The Yulex Patient Examination Glove is derived from the guayule bush, a desert plant native to the southwestern U.S.

Traditional latex gloves are made from the milky sap of a rubber tree, *Hevea brasiliensis*. The sap contains a protein that may trigger allergic skin and respiratory reactions. People who are allergic to traditional latex do not react on first exposure to guayule latex proteins, but the product will carry a warning about the potential for allergic reactions. (Source: FDA, April 24, 2008.)

**LipiScan for Imaging Plaque**

A new device now allows physicians to visualize inside a blood vessel to assess the fat content of plaque. The LipiScan Near-Infrared Catheter Imaging System (InfraReDx) can help physicians assess the chemical make-up of coronary artery plaques and help them identify those plaques with lipid cores. (Source: FDA, April 30, 2008.)

**Altrua Pacemakers**

The FDA has approved Boston Scientific’s Altrua family of pacemakers for treating heart rates below 60 beats per minute. The pacemaker can be programmed to reduce unnecessary right ventricular pacing. Electrograms provide diagnostic information about the heart rhythm before the onset of an arrhythmia, and a sensor treats chronotropic incompetence when the heart cannot regulate its rate appropriately in response to physical activity and emotional stress. (Source: Boston Scientific, May 8, 2008.)

**NEW MEDICAL DEVICES**

**Name:** Continuous Glucose-Monitoring System iPro Recorder

**Manufacturer:** Medtronic, Inc., Minneapolis, Minn.

**Approval Date:** January 29, 2008

**Use Classification:** Drug-eluting stents are used to treat narrowed coronary arteries.

**Description:** A tiny metal mesh tube is coated with a small amount of zotarolimus. The slow release of the drug over time prevents the artery from narrowing. The recorder assembles glucose levels in diabetic patients. The recorder measures and stores glucose values during a patient’s daily activities. After the recording period is completed, the patient returns to the physician’s office; the device is then removed, and the data are downloaded. The physician generates and interprets detailed reports to determine any needed changes to the patient’s therapy.

**Purpose:** The recorder helps doctors identify how everyday activities are affecting diabetes management.

**Benefit:** The iPro recorder is smaller, lighter in weight, and less time-consuming than previous glucose-monitoring recorders. Results are available in minutes, and improved ergonomics give patients added freedom when they are wearing the recorder. After the iPro recorder is worn for three days, physicians can review the data to optimize therapy. The device can be helpful in cases of inconsistently high and low glucose levels, hypoglycemia, and gestational diabetes. Physician services are reimbursed by Medicare in all 50 states.

**Sources:** www.pharmacyonesource.com; wwwp.medtronic.com

**Name:** Endeavor Zotarolimus-Eluting Coronary Stent System

**Manufacturer:** Medtronic, Inc., Minneapolis, Minn.

**Approval Date:** February 1, 2008

**Use Classification:** Drug-eluting stents are used to treat narrowed coronary arteries.

**Description:** A tiny metal mesh tube is coated with a small amount of zotarolimus. The slow release of the drug over time prevents the artery from narrowing. The recorder measures and stores glucose values during a patient’s daily activities. After the recording period is completed, the patient returns to the physician’s office; the device is then removed, and the data are downloaded. The physician generates and interprets detailed reports to determine any needed changes to the patient’s therapy.

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**Sources:** www.pharmacyonesource.com; wwwp.medtronic.com
rowing again when new tissue begins to form. Restenosis often results in the need for a second angioplasty. During angioplasty, a long, thin catheter is used to deliver the stent to the narrowed section of the coronary artery. After the stent is in place, the balloon is inflated and expands into the vessel wall to keep the artery open.

**Purpose:** The coated stent keeps the coronary artery open.

**Benefit:** In clinical studies, the Endeavor stent, compared with a bare-metal stent, reduced the number of major coronary events, including heart attacks, cardiac death, and repeated procedures to reopen the artery. The zotarolimus stent also reduced the restenosis rate by about half. This is the first drug-eluting stent approved since 2004 and the first one since the FDA convened its Circulatory System Devices Panel in 2006 to discuss evidence of the rare risk of blood clots after patients received drug-eluting stents. Medtronic plans to follow patients enrolled in six Endeavor trials for five years.

**Contraindications:** Patients who are allergic to zotarolimus, cobalt, nickel, chromium, or molybdenum should not receive an Endeavor stent. Caution is recommended for patients who have had recent cardiac surgery and for women who are nursing or who might be pregnant.

**Sources:** wwwp.medtronic.com; www.fda.gov

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**Name:** RestoreULTRA Neurostimulation System

**Manufacturer:** Medtronic, Inc., Minneapolis, Minn.

**Approval Date:** February 6, 2008

**Use Classification:** The neurostimulator is used to treat chronic, intractable back and leg pain.

**Description:** This neurostimulator is a fully implanted system with a rechargeable battery. Its compact shape allows for greater flexibility when physicians choose an implant site, and it is suitable for patients of all sizes.

**Purpose:** As the smallest and thinnest 16-electrode neurostimulator available, the device is intended for patients with pain after laminectomy or failed back surgery syndrome, unsuccessful disk surgery, degenerative disk disease, and other causes.

**Benefit:** A remote control feature allows patients to increase or decrease the intensity of electrical impulses and to customize therapy at home. Patients who use the medium setting for stimulation can go at least two weeks before they need to recharge the device, and they can move around when recharging it. The system’s small size provides improved patient comfort. Clinicians can treat several pain sites at the same time.

**Sources:** www.pharmacyonesource.com; www.medtronic.com