



## **(ACTONEL WITH CALCIUM/2)**

### **The Importance of Calcium**

When the body does not get enough calcium, it breaks down bone to help meet its calcium needs. According to the Surgeon General's Report on Bone Health and Osteoporosis, the average adult intake of calcium is approximately 700 mg daily, which is below the U.S. recommended daily allowance (RDA) of 1200 mg for women over 50. Many women who are taking a bisphosphonate may be able to make up this difference by taking a 500 mg calcium tablet, which is the amount of calcium found in *Actonel with Calcium* (risedronate sodium tablets with calcium carbonate tablets, USP).

### **Suggestions for Taking Calcium**

- Women aged 50 years and older should get a total of at least 1200 mg of calcium through dietary intake and, if necessary, a calcium supplement.
- Calcium, whether from diet or supplements, is absorbed best by the body when it is taken in doses of 500 mg or less of elemental calcium at one time.
- Calcium should not be taken at the same time as a bisphosphonate; bisphosphonate effectiveness decreases if calcium is taken within 30 minutes.
- Women should talk with their doctors about the bone health regimen that's right for them.

### **Selected Safety Information for *Actonel with Calcium***

Actonel with Calcium is indicated for the treatment and prevention of osteoporosis in postmenopausal women. Actonel with Calcium is contraindicated in patients with known hypersensitivity to any component of this product, or inability to stand or sit upright for at least 30 minutes. Actonel® (risedronate sodium tablets) and Calcium are contraindicated, respectively, in patients with hypocalcemia and hypercalcemia. These and other disturbances of bone and mineral metabolism should be effectively treated before starting Actonel with Calcium therapy. Actonel with Calcium is not recommended for use in patients with severe renal impairment (creatinine clearance < 30 mL/min). In patients with conditions causing or predisposing to hypercalcemia and in patients with a history of kidney stones, the administration of calcium should be assessed prior to prescribing and then monitored appropriately.

Bisphosphonates may cause upper gastrointestinal disorders such as dysphagia, esophagitis and esophageal or gastric ulcer. Patients should pay particular attention to the dosing instructions, as failure to take the drug according to instructions may compromise clinical benefits and may increase the risk of adverse events. Calcium may cause gastrointestinal adverse effects such as constipation, flatulence, nausea, abdominal pain, and bloating.

Among patients treated with bisphosphonates, there have been infrequent reports of severe and occasionally incapacitating bone, joint and/or muscle pain. Rare occurrences of osteonecrosis, primarily of the jaw (ONJ), have been reported in patients receiving bisphosphonates. Most ONJ cases have occurred in cancer patients undergoing dental procedures. In the majority of cases reported, patients had received intravenous bisphosphonate therapy.

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In clinical trials, Actonel was generally well tolerated. The overall incidence of adverse events with Actonel 5 mg daily was comparable to placebo. The most commonly reported adverse events regardless of causality were infection (primarily upper respiratory, placebo 29.7% vs Actonel 5 mg 29.9%), back pain (23.6% vs 26.1%), and arthralgia (21.1% vs 23.7%).

In a 1-year clinical trial comparing Actonel 35 mg Once-a-Week and Actonel 5 mg daily, the overall incidence of adverse events with the two dosing regimens was similar. The most commonly reported adverse events regardless of causality were infection (Actonel 35 mg 20.6% vs Actonel 5 mg 19.0%), arthralgia (14.2% vs 11.5%) and constipation (12.2% vs 12.5%). For more information about *Actonel with Calcium*, please see full prescribing information at [www.actonel.com](http://www.actonel.com).

### **About Osteoporosis**

Osteoporosis is a silent disease that affects millions of postmenopausal women, making their bones weak and more likely to fracture over time. In fact, in the U.S. today, 8 million women are estimated to already have osteoporosis, and almost 27 million more are estimated to have low bone mass, placing them at increased risk for fracture. Each year the incidence of osteoporosis-related fractures is greater than the incidence of heart attacks, strokes, and breast cancer combined. The good news is that there are prescription medications available that effectively reduce both vertebral and nonvertebral fracture risk.

### **About *Actonel with Calcium***

*Actonel with Calcium* is marketed by *The Alliance for Better Bone Health*, a collaboration between Procter & Gamble Pharmaceuticals and Aventis Pharmaceuticals, now a member of the sanofi-aventis Group. *Actonel with Calcium* is a prescription therapy to prevent and treat postmenopausal osteoporosis and works by slowing or stopping the cells that cause bone loss.

### **About the Harris Interactive® Survey**

Harris Interactive conducted the online and telephone survey between February 9 and 18, 2005 on behalf of *The Alliance for Better Bone Health* among 1,004 U.S. women aged 50 and over, of which 372 were bisphosphonate users. Data were weighted to be representative of the total U.S. adult female population aged 50 and over on the basis of age, race/ethnicity, education, region, income and propensity to be online. Though the online sample is not a probability sample, with probability samples of this size, Harris Interactive estimates with 95 percent certainty that the overall results have a sampling error of plus or minus 3 percentage points. Sampling error for the various sub-sample results, including bisphosphonate users (372); bisphosphonate users who also take calcium supplements (338); and calcium supplement users (755), is higher and varies.

### **About Harris Interactive®**

Harris Interactive Inc. ([www.harrisinteractive.com](http://www.harrisinteractive.com)), the 15<sup>th</sup> largest market research firm in the world, is a Rochester, NY-based global research company that blends premier strategic consulting with innovative and efficient methods of

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investigation, analysis and application. Known for *The Harris Poll*<sup>®</sup> and for pioneering Internet-based research methods, Harris Interactive conducts proprietary and public research to help its clients achieve clear, material and enduring results. Harris Interactive combines its intellectual capital, databases and technology to advance market leadership through its U.S. offices and wholly owned subsidiaries, HI Europe in London ([www.hieurope.com](http://www.hieurope.com)), Novatris in Paris ([www.novatris.com](http://www.novatris.com)), and through an independent global network of affiliate market research companies. EOE M/F/D/V.

#### **About the Information Resources, Inc. (IRI) Study**

This study conducted by Information Resources, Inc. (IRI) analyzed calcium purchasing practices of current bisphosphonate users over a one-year period. 498 households of women who filled a prescription for a bisphosphonate one year prior to and at least once during the current 52-week period were included in this study. Households were part of IRI's RxPulse™ Patient Panel, a subset of IRI's Consumer Network™ Panel, a nationally representative set of 70,000 households that scan all of their bar-coded purchases at home. Households within the RxPulse Patient Panel used scanning devices to record prescription information, including name of drug, strength and dose frequency, for each individual in their households. Data for supplement purchases included brand, calcium content (mg) and total tablet count.

The panel provided a single source of data for bisphosphonate usage as well as total number of calcium supplement tablets (including Tums®) purchased. Panel data are weighted to match U.S. demographics, and aggregate claimed purchases are verified through a comparison to store level scanner data. For this study, the supplement category was specifically examined and confirmed to fit within standard limits.

#### **About Information Resources, Inc.**

Information Resources, Inc. (IRI) is the leading global provider of enterprise market information solutions for the CPG, Retail, and Healthcare industries. IRI is the first company to leverage the power of real-time market information, advanced analytic insights, and enterprise performance management technology to improve the profitability and operational effectiveness of the world's leading CPG, retail and healthcare companies. The Company uniquely provides a total view of the market, enabling maximum business performance throughout the enterprise. IRI's solutions make the consumer-driven, real-time enterprise possible. More information is available at [www.infores.com](http://www.infores.com).

#### **About The Alliance for Better Bone Health**

*The Alliance for Better Bone Health* was formed by Procter & Gamble Pharmaceuticals and Aventis Pharmaceuticals, now a member of the sanofi-aventis Group, in May 1997 to promote bone health and disease awareness through numerous activities to support physicians and patients around the globe.

#### **About P&G (NYSE:PG)**

Two billion times a day, P&G brands touch the lives of people around the world. The company has one of the strongest portfolios of trusted, quality, leadership brands, including Pampers®, Tide®, Ariel®, Always®, Whisper®, Pantene®,

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Bounty®, Pringles®, Folgers®, Charmin®, Downy®, Lenor®, Iams®, Crest®, Actonel®, Olay® and Clairol Nice 'n Easy®, Head & Shoulders®, and Wella. The P&G community consists of almost 110,000 employees working in over 80 countries worldwide. Please visit <http://www.pg.com> for the latest news and in-depth information about P&G and its brands.

### **About sanofi-aventis**

The sanofi-aventis Group is the world's third largest pharmaceutical company, ranking number one in Europe. Backed by a world-class R&D organization, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine, and vaccines. The sanofi-aventis Group is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY)

*The sanofi-aventis Group conducts its business in the United States through its subsidiaries Sanofi-Synthélabo Inc., Aventis Pharmaceuticals Inc. and Sanofi Pasteur.*

*For The Procter & Gamble Company (the "Company"): All statements, other than statements of historical fact included in this release, are forward-looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995. In addition to the risks and uncertainties noted in this release, there are certain factors that could cause actual results to differ materially from those anticipated by some of the statements made. These include: (1) the ability to achieve business plans, including with respect to lower income consumers and growing existing sales and volume profitably despite high levels of competitive activity, especially with respect to the product categories and geographical markets (including developing markets) in which the Company has chosen to focus; (2) the ability to successfully execute, manage and integrate key acquisitions and mergers, including (i) the Domination and Profit Transfer Agreement with Wella, and (ii) the Company's agreement to merge with The Gillette Company, including obtaining the related required shareholder and regulatory approvals; (3) the ability to manage and maintain key customer relationships; (4) the ability to maintain key manufacturing and supply sources (including sole supplier and plant manufacturing sources); (5) the ability to successfully manage regulatory, tax and legal matters (including product liability, patent, and other intellectual property matters), and to resolve pending matters within current estimates; (6) the ability to successfully implement, achieve and sustain cost improvement plans in manufacturing and overhead areas, including the Company's outsourcing projects; (7) the ability to successfully manage currency (including currency issues in volatile countries), debt (including debt related to the Company's announced plan to repurchase shares of the Company's stock), interest rate and certain commodity cost exposures; (8) the ability to manage the continued global political and/or economic uncertainty and disruptions, especially in the Company's significant geographical markets, as well as any political and/or economic uncertainty and disruptions due to terrorist activities; (9) the ability to successfully manage the pattern of sales, including the variation in sales volume within periods; (10) the ability to successfully manage competitive factors, including prices, promotional incentives and trade terms for products; (11) the ability to obtain patents and respond to technological advances attained by competitors and patents granted to competitors; (12) the ability to successfully manage increases in the prices of raw materials used to make the Company's products; (13) the ability to stay close to consumers in an era of increased media fragmentation; and (14) the ability to stay on the leading edge of innovation. For additional information concerning factors that could cause actual results to materially differ from those projected herein, please refer to our most recent 10-K, 10-Q and 8-K reports.*

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