

PRODUCTS

Boot Supports Strains and Fractures

The Walking Boot can be used for severe ankle sprains and stable ankle fractures, as well as following cast removal and surgery. The boot is available in small, medium, and large sizes and can be worn on either foot. For more information, contact Swede-O Inc. by visiting www.swedeo.com or by calling 800-525-9339.

Fertility Treatment Launched

Menopur (menotropins for injection) is indicated for the development of multiple follicles and pregnancy in patients under-

going assisted reproductive technology procedures. This purified human menopausal gonadotropin contains equal amounts of follicle-stimulating hormone and luteinizing hormone. For more information, contact Ferring Pharmaceuticals Inc. by visiting www.ferring.com or by calling 888-337-7464.

Wheelchair Covers All Terrain

The Landeez wheelchair is designed for outdoor use. The plastic pneumatic wheels make it possible to ride over sand, gravel, soft soils, rocks, pebbles, forest

trails, and lightly packed snow. The wheelchair weighs 37 pounds and can be rapidly disassembled for storage or portability. For more information on this product, visit www.landeez.com or call 800-411-7789.

Company Sponsors Web Site

GlaxoSmithKline Consumer Healthcare Inc. has launched a Web site for physicians that offers dermatology tools and resources. The site provides clinical and prescribing information about several of the company’s drugs for dermatologic use. Physicians can also request product samples through the site. For more information, visit www.derm-professional.com.

One-Step TB Test Now Available

The QuantiFERON-TN Gold test is approved for the detection of immune responses to *Mycobacterium tuberculosis* infection. The one-step blood test provides a “yes” or “no” result that is unaffected by previous bacille Calmette-Guérin vaccination or cross-reactivity with most other mycobacteria. For more information, contact Cellestis Inc. by calling 800-519-4627 or by visiting www.cellestis.com.

Generic Niaspan Approved

A generic version of Niaspan (niacin extended-release tablets, Kos Pharmaceuticals Inc.) has been approved. The 500-mg, 750-mg, and 1,000-mg extended-release tablets are indicated for use as an adjunct to diet and other nonpharmacologic measures for reduction of elevated cholesterol levels when other nonpharmacologic measures have been inadequate. For more information, contact Barr Pharmaceuticals Inc. by calling 800-222-0190 or 201-930-3302.

Nonsteroidal Cream for Dermatitis

Prescription-only Atopiclair nonsteroidal cream is available for the management of chronic symptoms of mild to moderate atopic dermatitis. The cream’s safety has been demonstrated in babies as young as 1 month. For more information, contact Chester Valley Pharmaceuticals by visiting www.chestervalleypharma.com or by calling 877-287-7600.

Diabetes Management Software

DiaTrends (version 2.1.25) software allows quick entry of a wide variety of patient information pertinent to diabetes care. Data can be updated at clinical visits and trends can be tracked. Multiple reports can be generated. For more information, contact Overlook Software Inc. by visiting the company Web site, www.overlooksoftware.com, or by calling 336-274-0066.

Package Redesigned for EpiPen

The packaging of the EpiPen and EpiPen Jr. (epinephrine) autoinjectors has been redesigned to be more patient-friendly. The new design includes improved self-administration instructions on the auto-injector label, color-coded packaging, a new carrying case for needle protection, and an improved clip for carrying both doses at once. For more information, contact Dey L.P. by visiting www.epipen.com or by calling 707-224-3200.

Enbrel Indication Expanded

Enbrel (etanercept) is now indicated for the improvement of physical function in patients with psoriatic arthritis. For more information on this medication, contact Amgen Inc. and Wyeth Pharmaceuticals by visiting www.enbrel.com or by calling 888-436-2735.

At-Home Device for Acne

Zeno is an over-the-counter device designed for the treatment of mild to moderate acne. The device enables patients to deliver a dose of heat to pimples that is sufficient to destroy the *Propionibacterium acnes* bacteria but will not injure skin. The device will retail for more than \$200. For more information, contact Tyrell Inc. by visiting www.myzeno.com or by calling 888-469-9366.

Treatment of osteoporosis
Postmenopausal women

In two identically designed, three-year, placebo-controlled, double-blind, multicenter studies (United States and Multinational; n=994), discontinuation of therapy due to any clinical adverse experience occurred in 4.1% of 196 patients treated with FOSAMAX® (alendronate sodium) 10 mg/day and 6.0% of 397 patients treated with placebo. In the Fracture Intervention Trial (n=6459), discontinuation of therapy due to any clinical adverse experience occurred in 9.1% of 3236 patients treated with FOSAMAX 5 mg/day for 2 years and 10 mg/day for either one or two additional years and 10.1% of 3223 patients treated with placebo. Discontinuations due to upper gastrointestinal adverse experiences were: FOSAMAX, 3.2%; placebo, 2.7%. In these study populations, 49-54% had a history of gastrointestinal disorders at baseline and 54-89% used nonsteroidal anti-inflammatory drugs or aspirin at some time during the studies. Adverse experiences from these studies considered by the investigators as possibly, probably, or definitely drug related in B1% of patients treated with either FOSAMAX or placebo are presented in the following table.

Osteoporosis Treatment Studies in Postmenopausal Women Adverse Experiences Considered Possibly, Probably, or Definitely Drug Related by the Investigators and Reported in ≥1% of Patients				
	United States/Multinational Studies		Fracture Intervention Trial	
	FOSAMAX* % (n=196)	Placebo % (n=397)	FOSAMAX** % (n=3236)	Placebo % (n=3223)
<i>Gastrointestinal</i>				
abdominal pain	6.6	4.8	1.5	1.5
nausea	3.6	4.0	1.1	1.5
dyspepsia	3.6	3.5	1.1	1.2
constipation	3.1	1.8	0.0	0.2
diarrhea	3.1	1.8	0.6	0.3
flatulence	2.6	0.5	0.2	0.3
acid regurgitation	2.0	4.3	1.1	0.9
esophageal ulcer	1.5	0.0	0.1	0.1
vomiting	1.0	1.5	0.2	0.3
dysphagia	1.0	0.0	0.1	0.1
abdominal distention	1.0	0.8	0.0	0.0
gastritis	0.5	1.3	0.6	0.7
<i>Musculoskeletal</i>				
musculoskeletal (bone, muscle or joint) pain	4.1	2.5	0.4	0.3
muscle cramp	0.0	1.0	0.2	0.1
<i>Nervous System/Psychiatric</i>				
headache	2.6	1.5	0.2	0.2
dizziness	0.0	1.0	0.0	0.1
<i>Special Senses</i>				
taste perversion	0.5	1.0	0.1	0.0

*10 mg/day for three years

**5 mg/day for 2 years and 10 mg/day for either 1 or 2 additional years

Rarely, rash and erythema have occurred.

One patient treated with FOSAMAX (10 mg/day), who had a history of peptic ulcer disease and gastrectomy and who was taking concomitant aspirin developed an anastomotic ulcer with mild hemorrhage, which was considered drug related. Aspirin and FOSAMAX were discontinued and the patient recovered.

The adverse experience profile was similar for the 401 patients treated with either 5 or 20 mg doses of FOSAMAX in the United States and Multinational studies. The adverse experience profile for the 296 patients who received continued treatment with either 5 or 10 mg doses of FOSAMAX in the two-year extension of these studies (treatment years 4 and 5) was similar to that observed during the three-year placebo-controlled period. During the extension period, of the 151 patients treated with FOSAMAX 10 mg/day, the proportion of patients who discontinued therapy due to any clinical adverse experience was similar to that during the first three years of the study.

In a one-year, double-blind, multicenter study, the overall safety and tolerability profiles of once weekly FOSAMAX 70 mg and FOSAMAX 10 mg daily were similar. The adverse experiences considered by the investigators as possibly, probably, or definitely drug related in B1% of patients in either treatment group are presented in the following table.

Osteoporosis Treatment Studies in Postmenopausal Women Adverse Experiences Considered Possibly, Probably, or Definitely Drug Related by the Investigators and Reported in ≥1% of Patients			
	Once Weekly FOSAMAX 70 mg		FOSAMAX 10 mg/day
	% (n=519)	% (n=370)	% (n=370)
<i>Gastrointestinal</i>			
abdominal pain	3.7	3.0	
dyspepsia	2.7	2.2	
acid regurgitation	1.9	2.4	
nausea	1.9	2.4	
abdominal distention	1.0	1.4	
constipation	0.8	1.6	
flatulence	0.4	1.6	
gastritis	0.2	1.1	
gastric ulcer	0.0	1.1	
<i>Musculoskeletal</i>			
musculoskeletal (bone, muscle, joint) pain	2.9	3.2	
muscle cramp	0.2	1.1	

Men

In two placebo-controlled, double-blind, multicenter studies in men (a two-year study of FOSAMAX 10 mg/day and a one-year study of once weekly FOSAMAX 70 mg) the rates of discontinuation of therapy due to any clinical adverse experience were 2.7% for FOSAMAX 10 mg/day vs. 10.5% for placebo, and 6.4% for once weekly FOSAMAX 70 mg vs. 8.6% for placebo. The adverse experiences considered by the investigators as possibly, probably, or definitely drug related in B2% of patients treated with either FOSAMAX or placebo are presented in the following table.

Osteoporosis Studies in Men Adverse Experiences Considered Possibly, Probably, or Definitely Drug Related by the Investigators and Reported in ≥2% of Patients				
	Two-year Study		One-year Study	
	FOSAMAX 10 mg/day % (n=146)	Placebo % (n=95)	Once Weekly FOSAMAX 70 mg % (n=109)	Placebo % (n=58)
<i>Gastrointestinal</i>				
acid regurgitation	4.1	3.2	0.0	0.0
flatulence	4.1	1.1	0.0	0.0
gastroesophageal reflux disease	0.7	3.2	2.8	0.0
dyspepsia	3.4	0.0	2.8	1.7
diarrhea	1.4	1.1	2.8	0.0
abdominal pain	2.1	1.1	0.9	3.4
nausea	2.1	0.0	0.0	0.0

Concomitant use with estrogen/hormone replacement therapy

In two studies (of one and two years' duration) of postmenopausal osteoporotic women (total: n=853), the safety and tolerability profile of combined treatment with FOSAMAX 10 mg once daily and estrogen ± progestin (n=354) was consistent with those of the individual treatments.

Other studies with FOSAMAX® (alendronate sodium)

Prevention of osteoporosis in postmenopausal women

The safety of FOSAMAX 5 mg/day in postmenopausal women 40-60 years of age has been evaluated in three double-blind, placebo-controlled studies involving over 1,400 patients randomized to receive FOSAMAX for either two or three years. In these studies the overall safety profiles of FOSAMAX 5 mg/day and placebo were similar. Discontinuation of therapy due to any clinical adverse experience occurred in 7.5% of 642 patients treated with FOSAMAX 5 mg/day and 5.7% of 648 patients treated with placebo.

In a one-year, double-blind, multicenter study, the overall safety and tolerability profiles of once weekly FOSAMAX 35 mg and FOSAMAX 5 mg daily were similar.

The adverse experiences from these studies considered by the investigators as possibly, probably, or definitely drug related in B1% of patients treated with either once weekly FOSAMAX 35 mg, FOSAMAX 5 mg/day or placebo are presented in the following table.

Osteoporosis Prevention Studies in Postmenopausal Women Adverse Experiences Considered Possibly, Probably, or Definitely Drug Related by the Investigators and Reported in ≥1% of Patients				
	Two/Three-Year Studies		One-Year Study	
	FOSAMAX 5 mg/day % (n=642)	Placebo % (n=648)	FOSAMAX 5 mg/day % (n=361)	Once Weekly FOSAMAX 35 mg % (n=362)
<i>Gastrointestinal</i>				
dyspepsia	1.9	1.4	2.2	1.7
abdominal pain	1.7	3.4	4.2	2.2
acid regurgitation	1.4	2.5	4.2	4.7
nausea	1.4	1.4	2.5	1.4
diarrhea	1.1	1.7	1.1	0.6
constipation	0.9	0.5	1.7	0.3
abdominal distention	0.2	0.3	1.4	1.1
<i>Musculoskeletal</i>				
musculoskeletal (bone, muscle or joint) pain	0.8	0.9	1.9	2.2

Treatment of glucocorticoid-induced osteoporosis

In two, one-year, placebo-controlled, double-blind, multicenter studies in patients receiving glucocorticoid treatment, the overall safety and tolerability profiles of FOSAMAX 5 and 10 mg/day were generally similar to that of placebo. The adverse experiences considered by the investigators as possibly, probably, or definitely drug related in B1% of patients treated with either FOSAMAX 5 or 10 mg/day or placebo are presented in the following table.

One-Year Studies in Glucocorticoid-Treated Patients Adverse Experiences Considered Possibly, Probably, or Definitely Drug Related by the Investigators and Reported in ≥1% of Patients			
	FOSAMAX 10 mg/day % (n=157)	FOSAMAX 5 mg/day % (n=161)	Placebo % (n=159)
<i>Gastrointestinal</i>			
abdominal pain	3.2	1.9	0.0
acid regurgitation	2.5	1.9	1.3
constipation	1.3	0.6	0.0
melena	1.3	0.0	0.0
nausea	0.6	1.2	0.6
diarrhea	0.0	0.0	1.3
<i>Nervous System/Psychiatric</i>			
headache	0.6	0.0	1.3

The overall safety and tolerability profile in the glucocorticoid-induced osteoporosis population that continued therapy for the second year of the studies (FOSAMAX: n=147) was consistent with that observed in the first year.

Paget's disease of bone

In clinical studies (osteoporosis and Paget's disease), adverse experiences reported in 175 patients taking FOSAMAX 40 mg/day for 3-12 months were similar to those in postmenopausal women treated with FOSAMAX 10 mg/day. However, there was an apparent increased incidence of upper gastrointestinal adverse experiences in patients taking FOSAMAX 40 mg/day (17.7% FOSAMAX vs. 10.2% placebo). One case of esophagitis and two cases of gastritis resulted in discontinuation of treatment.

Additionally, musculoskeletal (bone, muscle or joint) pain, which has been described in patients with Paget's disease treated with other bisphosphonates, was considered by the investigators as possibly, probably, or definitely drug related in approximately 6% of patients treated with FOSAMAX 40 mg/day versus approximately 1% of patients treated with placebo, but rarely resulted in discontinuation of therapy. Discontinuation of therapy due to any clinical adverse experience occurred in 6.4% of patients with Paget's disease treated with FOSAMAX 40 mg/day and 2.4% of patients treated with placebo.

Laboratory Test Findings

In double-blind, multicenter, controlled studies, asymptomatic, mild, and transient decreases in serum calcium and phosphate were observed in approximately 18% and 10%, respectively, of patients taking FOSAMAX versus approximately 12% and 3% of those taking placebo. However, the incidences of decreases in serum calcium to <8.0 mg/dL (2.0 mM) and serum phosphate to A2.0 mg/dL (0.65 mM) were similar in both treatment groups.

FOSAMAX PLUS D™ (alendronate sodium/cholecalciferol)

In a fifteen week double-blind, multinational study in osteoporotic postmenopausal women (n=682) and men (n=35), the safety profile of FOSAMAX PLUS D was similar to that of FOSAMAX once weekly 70 mg.

Post-Marketing Experience

The following adverse reactions have been reported in post-marketing use with alendronate:

Body as a Whole: hypersensitivity reactions including urticaria and rarely angioedema. Transient symptoms of myalgia, malaise and rarely, fever have been reported with alendronate, typically in association with initiation of treatment. Rarely, symptomatic hypocalcemia has occurred, generally in association with predisposing conditions.

Gastrointestinal: esophagitis, esophageal erosions, esophageal ulcers, rarely esophageal stricture or perforation, and oropharyngeal ulceration. Gastric or duodenal ulcers, some severe and with complications have also been reported (see WARNINGS, PRECAUTIONS, *Information for Patients*, and DOSAGE AND ADMINISTRATION).

Localized osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported rarely (see PRECAUTIONS, *Dental*).

Musculoskeletal: bone, joint, and/or muscle pain, occasionally severe, and rarely incapacitating (see PRECAUTIONS, *Musculoskeletal Pain*).

Skin: rash (occasionally with photosensitivity), pruritus, rarely severe skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

Special Senses: rarely uveitis, scleritis or episcleritis.

For more detailed information, please read the Prescribing Information.

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