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PRESS RELEASE

FOR IMMEDIATE RELEASE

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American Regent Announces the Availability of Pamidronate Disodium Injection

Shirley, NY – (July 6, 2010): American Regent, Inc. is pleased to announce that, following its purchase of PharmaForce Inc. (Columbus, OH) in December 2009, Pamidronate Disodium Injection is now available under the American Regent label with a new NDC.

Pamidronate Disodium Injection is “AP” Rated to Aredia® (NOVARTIS) and is Latex and Preservative Free.

Product	Strength	NDC Number	Shelf Pack
Pamidronate Disodium Injection	30 mg/10 mL Single Dose Vial (3 mg/mL)	00517-0745-01 Previous NDC: 40042-019-10	1
Pamidronate Disodium Injection	90 mg/10 mL Single Dose Vial (9 mg/mL)	00517-0746-01 Previous NDC: 40042-017-20	1

Headquartered in Shirley, NY, American Regent, Inc., distributes over 80 pharmaceutical products under the PharmaForce or their own label, including Venofer (iron sucrose injection, USP) the #1 selling IV iron therapy in the U.S. For more information about this product or other American Regent or PharmaForce products, please contact our customer service department at 1-800-645-1706.

Source: American Regent, Inc.

See accompanying Full Prescribing Information

IMPORTANT SAFETY INFORMATION

Pamidronate disodium injection is contraindicated in patients with clinically significant hypersensitivity to pamidronate disodium or other bisphosphonates.

Due to the risk of clinically significant deterioration in renal function, which may progress to renal failure, single doses of pamidronate disodium injection should not exceed 90 mg and the duration of infusion should be no less than 2 hours. After the initial or a single dose of pamidronate disodium injection, renal deterioration, progression to renal failure, and dialysis has been reported in patients. Patients treated with pamidronate disodium injection, particularly those with multiple myeloma and breast cancer, have reported focal segmental glomerulosclerosis (including the collapsing variant) with or without nephrotic syndrome, which may lead to renal failure, and some had gradual renal status improvement upon discontinuation of pamidronate disodium injection.

Serum creatinine should be assessed prior to each treatment, and those with bone metastases should have the dose withheld if renal function has deteriorated.

Pamidronate disodium injection should not be used during pregnancy. Women of childbearing potential should be advised to avoid becoming pregnant.

Pamidronate sodium injection is excreted intact primarily via the kidney, and the risk of renal adverse reactions may be greater in patients with impaired renal function. Caution is indicated when pamidronate sodium injection is used with other potentially nephrotoxic drugs, and in multiple myeloma patients, the risk of renal dysfunction is increased when pamidronate disodium injection is combined with thalidomide.

Osteonecrosis of the jaw (ONJ) has been reported predominantly in cancer patients treated with intravenous bisphosphonates, including pamidronate disodium injection. Many of these patients were also receiving chemotherapy and corticosteroids which may be risk factors for ONJ. Postmarketing experience and the literature suggest a greater frequency of reports of ONJ based on tumor type (advanced breast cancer, multiple myeloma), and dental status (dental extraction, periodontal disease, local trauma including poorly fitting dentures). Many reports of ONJ involved patients with signs of local infection including osteomyelitis. While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition.

In post-marketing experience, severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking bisphosphonates. Symptoms were generally relieved after stopping treatment, and a subset of patients had symptoms recur after rechallenge with pamidronate disodium injection or another bisphosphonate.

Closely monitor serum calcium, phosphate, magnesium, potassium, creatinine, and CBC, differential, and hematocrit/hemoglobin following initiation of treatment with pamidronate disodium injection. Asymptomatic hypophosphatemia (12%), hypokalemia (7%), hypomagnesemia (11%) and hypocalcemia (5-12%) were reported in patients treated with pamidronate disodium injection. Rare cases of symptomatic hypocalcemia (including tetany) have been reported; short-term calcium therapy may be necessary. Patients with a history of thyroid surgery may have relative hypoparathyroidism that may predispose to hypocalcemia with pamidronate disodium injection.

In post-marketing experience, rare instances of allergic manifestations have been reported, including hypotension, dyspnea, or angioedema, and, very rarely, anaphylactic shock.

The most common adverse events (>15%) in bone metastases clinical trials, regardless of causality, were as follows: Asthenia, fatigue, diarrhea, dyspepsia, fluid overload, abdominal pain, anorexia, constipation, metastases, insomnia, nausea, vomiting, urinary tract infection, skeletal pain, fever, headache, coughing, upper respiratory tract infection, anemia, granulocytopenia, myalgias, sinusitis, and dyspnea. The most common adverse events (>15%) in the Hypercalcemia of Malignancy trials, regardless of causality, include: Fluid overload, generalized pain, hypertension, abdominal pain, anorexia, constipation, nausea, vomiting, urinary tract infection, bone pain, anemia, hypokalemia, hypomagnesemia, and hypophosphatemia. The most common adverse events (>10%) in the Paget's Disease trials, regardless of causality, include: Hypertension, arthrosis, bone pain, and headache.

In hypercalcemia of malignancy trials, rare cases of uveitis, iritis, scleritis, and episcleritis have been reported, and one case each of uveitis and scleritis were found to recur upon separate rechallenge. In the absence of hypercalcemia, patients at risk of calcium or vitamin D deficiency with predominantly lytic bone metastases or multiple myeloma and patients with Paget's disease of the bone should be administered an oral calcium and vitamin D supplement.