Osteoporosis Medication Aclasta Associated With Renal Impairment And Kidney Failure

Novartis Sends "Dear Doctor" Letter To Canadian Physicians With Health Canada Endorsed Safety Information

(Posted by Tom Lamb at www.DrugInjuryWatch.com on October 25, 2010; see http://bit.ly/aQf1Ur)

In 2007 Aclasta (zoledronic acid 5mg) was approved by the FDA under the brand name Aclasta® Injection as the first and only once-yearly medicine for postmenopausal osteoporosis. Aclasta is given as a once-yearly 15-minute intravenous (IV) infusion.

From this August 22, 2007 news article, "Aclasta Receives US FDA Approval As First And Only Once-Yearly Treatment For Women With Postmenopausal Osteoporosis", we get some background about the efficacy and safety information known at the time of FDA approval in 2007:

> The US approval comes a few weeks after the Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending approval for the medicine in the European Union. The European Medicines Agency (EMEA) generally follows the CHMP's recommendations and is expected to issue marketing authorisation within three months.
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> The regulatory submissions were based on efficacy and safety data from the three-year Pivotal Fracture Trial, which showed that Aclasta increases bone strength and reduces fractures in areas of the body typically affected by osteoporosis, including the hip, spine and non-spine (i.e. hip, wrist, arm, leg, rib). Aclasta is the only treatment proven to reduce fractures across all of these key sites.

Coming forward to the present time, on October 14, 2010 Health Canada issued a MedEffect e-Notice, "ACLASTA (zoledronic acid 5mg/100mL) solution for intravenous infusion - Association with renal dysfunction - Novartis Pharmaceuticals Canada Inc.", which provided this new safety information about Aclasta:

> Novartis in collaboration with Health Canada, is notifying healthcare professionals and the public of reports of renal impairment and renal failure requiring dialysis or with fatal outcome that occurred in patients with history of renal impairment or other risk factors receiving ACLASTA (zoledronic acid).

The Health Canada web site also provided links to a so-called "Dear Doctor" letter about Aclasta sent by Novartis to Canadian health care professionals on or about October 12, 2010 and a public information page about this kidney / renal side effect alert intended for patients.

We will be watching for a similar MedWatch Alert about Aclasta from the FDA and/or a "Dear Doctor" letter from Novartis to American health care professionals about the 265 spontaneous reports of renal impairment -- ranging from renal dysfunction manifested as deterioration in renal function to acute renal failure, or kidney failure, requiring dialysis or resulting in death -- that prompted Health Canada to issue its Aclasta MedEffect e-Notice in mid-October 2010.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
http://www.DrugInjuryWatch.com