CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

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New Osteoporosis Treatment

The medications most often prescribed for the treatment of osteoporosis are the oral bisphosphonates (BPs)- Fosamax, its generic version alendronate, Actonel, and Boniva. However, in order to be well absorbed and get to your bones, these must be taken on an empty stomach the first thing in the morning after an overnight fast, followed by waiting at least 30 to 60 minutes before eating. Needless to say, this is not always easy to get right, and a hardship for those of us who have a strong urge to have a cup of coffee or eat something as soon as we get up. There is now a solution for this annoying problem: Atelvia.

Atelvia is a very clever formation of risedronate, the same drug that is in Actonel. The difference is that Atelvia is taken immediately after breakfast, allowing you to enjoy your morning coffee and whatever you want to eat before you take your medication.

The science behind pill-making It requires fascinating. thorough understanding of the pharmacological properties of each and knowledge of drug materials that can be used in manufacturing. With the BP class of drugs used to treat osteoporosis, it is important to realize that they are very poorly absorbed. When a pill is swallowed, only one-half of actually gets into bloodstream and on to your bones. If the pill encounters anything other than water and natural

stomach juices, it will not be absorbed at all. This is the reason that it must be taken with a glass of plain water. If it is swallowed with coffee, orange juice, or milk, the medication in the pill will be trapped in the intestines and be very poorly absorbed, if at all. It is even possible that swallowing the pill with water that contains a lot of minerals may interfere with absorption. Also, any food in your stomach will reduce or totally block absorption. This is why an overnight fast is so important when taking BPs.

So how does Atelvia overcome these problems? First, there is a delayed release coating on the tablet that only dissolves at a pH above 5.5. This allows it to pass through the esophagus and stomach and into the small intestine before dissolving. Second, it contains a "chelating agent" that binds to calcium and other elements at the site of drug release. thereby making the medication more available for absorption and transport to the bones. The end result is that Atelvia has an effect on bone density and bone metabolism that is very similar Actonel taken as directed. Research studies have shown no difference in side effects between Atelvia and Actonel. It is likely that the effect on bone strength and the reduction in the risk of fractures is also similar with the two medications.

We are fortunate to now have many choices for the treatment of osteoporosis. Ask your doctor which ones might be good choices for you.

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Clinical Research

Our clinical research program is recruiting patients to participate in studies to test new medications and evaluate new uses for currently available drugs. By participating in a study you will have the opportunity to use one of these medications, have free examinations and tests, and receive reimbursement for your time and travel. If this interests you, please take a few minutes to read the major criteria for participation.

If you think you may qualify for a study or are interested in participating in a research study, call a study specialist at (505) 923-3232.

Feel free to pass this newsletter to a friend or relative who may be interested. The drug study information will be updated quarterly, since we are continually starting new studies and closing out old ones. We do studies for high blood pressure, high cholesterol, osteoarthritis, osteoporosis, heartburn, GERD, irritable bowel syndrome and others. Please fell free to call and give your information to a study specialist for consideration for future studies. If there is nothing for you now, there may be next time.

Gout with Heart Problems

A research study comparing two approved medications for those diagnosed with gout who also have cardiac risk such as diabetes, previous heart attack or stroke:

- Are between 45 and 85 years old
- Suffering from gout whether or not you are currently taking daily medication

 Takeda TMX-67-301

Diabetes

A research study of an investigational medication for diabetes. You may be eligible to participate if you are:

- Are a diabetic age over the age of 18
- Your diabetes is not adequately controlled on your current regimen
- Your current regimen does not include Insulin, Januvia or Byetta

Lilly-GBDN

Diabetes

A research study of an investigational medication for diabetes. You may be eligible to participate if you are:

- Are a diabetic age 25 or older
- Your diabetes is not adequately controlled on your current regime JNJ-3010

Gout

This is a research study of an investigational medication for gout. You may be eligible to participate if you are:

- A between the age of 45-85 years old
- Have been diagnosed with gout

BCX-203

Healthy Women Osteoporosis Study

This is a research study to study the effect of a medication on bones. You may be eligible to participate if you are:

- A postmenopausal women 45 to 75 years old
- Have not been diagnosed with osteoporosis
- Are at least 5 years post menopausal

Takeda 390104

Diabetes On Metformin Only

This is a clinical trial to assess the safety and efficacy of an investigational Medication. Study may last up to 1 year. Study related medication is provided at no charge and time and travel expenses are available for qualified participants. You may be eligible to participate if you:

- Are age 18 or over
- Are a diabetic
- Currently taking only metformin for diabetes control

Shionogi



Woman To Woman By Julia Chavez, CNP

Diabetes, Diet, and Dietitians, Oh My

If you have developed diabetes or you have trouble controlling your weight, who are you going to talk to? As a person with diabetes it becomes complicated and stressful trying to decide what you can or cannot eat. Other factors involved in dietary decisions include controlling your blood sugar as well as eating the healthiest foods to control your blood pressure and your cholesterol. All of these decisions can add to the stress level, which can make the diabetes worse.

Your provider may refer you to a Registered Dietitian (RD) or to a Certified Diabetes Educator (CDE) so that you can have the benefit of the specialized care that you need. A registered dietitian (RD) is a food and nutrition expert who has at least a bachelor's degree and probably a master's degree in a course of study that has been approved by the American Diabetic Association. Most doctors do not have the training, education, or time to provide this service, so if you are referred to a CDE or an RD, make the most of the time and expertise that they have to offer.

If you are interested in getting a referral, please talk to your provider at your next office visit.

If you enjoyed this newsletter and would like to be placed on an electronic mailing list, email ybrusuelas@nmbonecare.com. The newsletter is produced on a quarterly basis.

Osteoporosis Foundation of New Mexico Educational Presentations

Manzano Mesa Multigenerational Center 501 Elizabeth SE Albuquerque, NM 87123 (505) 275-8731

1:30-3:00 PM

2011 Meetings:

February 10, 2011 Molly Grady Topic: "The Benefits of T'ai Chi Chih that relate to Osteoporosis and Balance"

May 12, 2011 Isabel Torres, RT Topic: "Bone Density Testing-What to Expect"

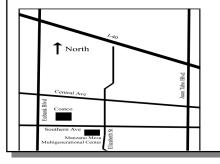
> August 11, 2011 George Fraser, Fifty n' Fit Topic: "Smart Exercises for Osteoporosis"

November 10, 2011 E. Michael Lewiecki, MD Topic: "New Treatments in Osteoporosis"

These meetings are open to the public. It is a great opportunity to talk to osteoporosis experts for as long as you want. There is limited space, so please sign up by calling 275-8731 in order to attend. A \$1 fee is collected in order to cover the cost of educational material.

Consider attending if:

- You have osteoporosis,
- You have a loved one with osteoporosis, or
- You are interested in learning more about osteoporosis.



OSTEOPOROSIS CORNER

Ask Dr. Mike Lewiecki about OSTEOPOROSIS

More on Vitamin D

Dear Dr. Lewiecki— I have been taking a drug for treatment of osteoporosis for 3 years. I just had a bone density test. My doctor said she was not happy with the results and now wants to change my medicine. I am very upset. Why wasn't the medicine working and what should I do? Please help. Amanda R., Durango, CO.

Dear Amanda – You raise many issues that are often perplexing to physicians caring for patients with osteoporosis. Let's go through some of them one at time.

First. what is a poor response to therapy? The purpose of taking an osteoporosis medication is to reduce fracture by improving bone strength. Since we cannot measure bone strength directly, we usually estimate it by measuring bone density. We know research studies that if the drug stabilizes or increases bone density, the risk of fracture goes down. A poor response to therapy is when bone density

goes down significantly, with emphasis on significantly (see sidebar to the right of this column).

Second, how should a patient with significant bone loss be evaluated? Bone loss can occur when the medication is not taken regularly, not taken correctly, or when calcium and vitamin D intake is too low. Sometimes all of these things are done correctly, but there is a problem with poor absorption. In some cases, other medical problems have developed or other drugs are taken that are harmful to bones. Usually, a few simple laboratory tests can help to sort this out.

Finally, what should be done to correct the situation when there is a poor response to therapy? Any correctable problems that are found on the evaluation should be addressed. Sometimes a switch from a pill to injectable medications will help. In situations where the risk of fractures is very high, a change to a much more potent drug may help. The best choice for you should be decided after a detailed discussion of the expected benefit and potential risk of treatment.

Mike Lewiecki

QUALITY MATTERS

It is difficult to define quality, but most of us know it when we see it. Ouality in bone density testing is very important, but not always so easy to see. It involves things such as instrument calibration, measurement of bone density in "phantoms," quality assurance protocols, precision of "least assessment, calculation significant change," proper patient positioning, correct image analysis, and the use of the most current standards for diagnostic classification and fracture risk assessment.

Poor quality bone density tests can be harmful. For example, an incorrect diagnosis of osteoporosis may lead to treatment that is not needed. An incorrect report of bone loss while on treatment could lead to expensive tests and a change in therapy that may not be necessary.

To stay current, technologists and physicians involved with bone density testing must be trained to do perform and interpret these measurements properly and maintain these skills through continuing medical education.

How can you tell if you are getting a good quality bone density test? Ask about certification from the International Society for Clinical Densitometry. Ask whether precision testing has been done. Ask about the number for the "Least Significant Change." Be sure that the test that you get is a good reliable measurement that can be used in making the best possible decisions for your care.



Support osteoporosis education in New Mexico. Help to reduce the burden of osteoporotic fractures. Osteoporosis Foundation of New Mexico is a local non-profit 501(c)(3) foundation. Consider a tax-deductible donation or bequest. Donations may be mailed to Osteoporosis Foundation of New Mexico at 300 Oak St. NE, Albuquerque, NM 87106. For more information, call Yvonne Brusuelas at 505-855-5627.