

CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

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Once-a-Year Osteoporosis Treatment Now Approved

The US Food and Drug Administration (FDA) recently announced the approval of Reclast for the treatment of postmenopausal osteoporosis. This medication, also called zoledronic acid or zoledronate, is given as an intravenous (IV) infusion over about 20 minutes every 12 months. New Mexico Clinical Research & Osteoporosis Center participated in clinical trials for Reclast, which showed an increase in bone density and reduction in the risk of fracture at the spine, hip, and other non-spine bones.

This drug is classified as a bisphosphonate- the family of drugs that includes familiar names such as Fosamax, Actonel, and Boniva. These are the medications most often used to treat osteoporosis, a disease that results in fragile bones that are at increased risk of breaking (fracturing) under circumstances where normal bone would not break. Fractures due to osteoporosis may cause persistent pain, loss of independence, and death. Fortunately, osteoporosis can now be easily detected with a simple bone density test, and medications are available to prevent and treat osteoporosis.

Reclast is one of two

injectable bisphosphonate medications approved for the treatment of osteoporosis in postmenopausal women, the other being Boniva, which is given every 3 months as an IV injection over 15-30 seconds.

Who should be treated with one of these? Usually it is for someone who is not able to take similar drugs in pill form due to previous side effects, problems with the esophagus or stomach, or difficulty absorbing the medication due to an intestinal disease or past surgery for obesity or ulcers.

It seems very remarkable that this medication can work for as long as 12 months after a single dose. There are no other drugs in common use that have this unusual characteristic. It is possible because of the strong attachment of the medicine to bone after the injection. It continues to work because the bone itself acts as a sort of "time-release capsule" that stores the medication and releases it when needed.

If you think that you may benefit from such an injectable medication for osteoporosis, ask your doctor for more information.

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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, call the Research Dept. 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. If there is nothing for you now, there may be next time.

Treatment of Fibromyalgia

This is a 6-8 week study for an investigational medication for the treatment of Fibromyalgia. **You may be eligible to participate if you are:**

- Female Between 18-75 years old
- Suffering from unexplained widespread pain for at least 3 months Allergan-203818

Treatment of Postmenopausal Hot Flashes

A 12-week research study for an investigational hormonal treatment for women suffering from post menopausal hot flashes. **You may be eligible to participate if you are:**

- Postmenopausal female 45-60 years old
- Suffer from at least 7 hot flashes in a 24 hour period GSK SRM105106

Osteoarthritis of the Knee

This is an 18 week research study to see if an investigational treatment for osteoarthritis of the knee. **You may be eligible to participate if you are:**

- Are at least 40 years old;
- Have been diagnosed with or think you might have osteoarthritis of the knee
- Take medication for relief of pain in your knee at least 15 days a month

Combinatorx

Severe Osteoporosis

This is a one-year clinical research trial testing an investigational treatment for severe osteoporosis in postmenopausal women. **You may be eligible to participate if you are:**

- A post-menopausal female between 45-89 years of age
- Have been diagnosed with severe osteoporosis 2293

Osteopenia

This is a research study using an investigational Vitamin D compound for the treatment of low bone density. **You may be eligible to participate if you are:**

- If you are a postmenopausal woman between the ages of 55 and 80. 2295

Treatment for Irritable Bowel Syndrome

This is a 19-week, study of investigation medication in female subjects with Diarrhea predominant or alternating Irritable Bowel Syndrome.

You may be eligible to participate if you are:

- A woman between 18 and 65
- Suffering from abdominal pain or discomfort associated with diarrhea more than 3 days per month. VPI-TOFP-203

Insomnia

This is a 2-4-week, randomized, placebo controlled study for safety and efficacy of an investigational medication in patients with primary chronic insomnia. Upon completion of this study you may be able to participate in a 52-week open-label extension study.

You may qualify to participate if you are:

- Between the ages of 18 and 64
- Suffer from insomnia at least 3 nights a week for the past year. Org176001



**Woman
To
Woman**
By
Julia Chavez, CNP

GET THE MOST OUT OF YOUR OFFICE VISIT

The following are just a few tips to help you get the most out of your doctor's visit.

- 1.) **Make your list of questions and problems before you come in so that you won't forget what you intended to ask.**
- 2.) **Prioritize your list so that the most important issues get addressed first. Don't save the "best for the last" or you may end up running out of time.**
- 3.) **Try to limit your list to the three most important issues and then if there is time for more go ahead and mention them. If you run out of time you may have to reschedule to address the next three problems.**
- 4.) **Be aware that if you mention something as a problem, you may end up having lab tests or other x-rays or procedures ordered. If you just feel like mentioning something but you don't want tests or procedures ordered, be clear with the provider about your intentions.**
- 5.) **Be open and honest about your problems and about the medications that you take. The provider cannot read your mind and doesn't have time for "guessing games".**
- 6.) **Bring in an updated list of your current medications including over-the-counter and herbal preparations.**
- 7.) **If you will be needing renewals on your prescriptions write down the medication name and strength and how often you take it or bring in the prescription bottles.**
- 8.) **We strive to make your office visit as pleasant as possible and want you to have the best possible experience.**

Osteoporosis Foundation of New Mexico

Educational Presentations

2nd Thursday of every month:
Manzano Mesa
Multigenerational Center
501 Elizabeth SE
Albuquerque, NM 87123
(505) 275-8731

1:30 - 3:00PM

October 11, 2007

Steven Wong

Topic: "Dreaming the Bones: A
Jungian Approach to Osteoporosis"

November 8, 2007

Dr. Todd Pickman

Topic: "How to Prevent
Osteoarthritis for Life"

December 13, 2007

Jan Newquest, RD, LD

Topic: "Diet and Calcium for
Osteoporosis Health"

These meetings are open to the public. It is a great opportunity to talk to osteoporosis experts for as long as you want.

Consider attending if:

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

To RSVP your
attendance call
338-6333

www.osteoporosisfoundationm.org

Ask Dr. Mike Lewiecki about . . . OSTEOPOROSIS

Dear Dr. Lewiecki– I am completely befuddled by the many frightening news stories about side effects of medications. I have osteoporosis. I don't want to break bones and end up being stooped over like my mother, but I am afraid to take medication because of what I hear about side effects. What should I do?

Victoria C., Albuquerque, NM.

Dear Victoria – You are right that there are scary things in the news- not only about healthcare but the world in general. How can any of us deal with this, when even the experts do not seem to agree on what is safe and what is not?

With medication, you must be sure that you have the facts straight, and then you have to put them in proper perspective. What you read in the newspaper, hear on TV, and find on the Internet, is often only part of the story, and sometimes incorrect. To be sure that you have the facts straight, you need a reliable and reputable source of information. Some usually good medical sources are publications or

websites from medical institutions such as Harvard or the Mayo Clinic. Even better, ask your doctor for advice what to do or where else to look.

It may be true that a very bad side effect is possible from taking a drug, but you must put it into its proper perspective. You need to know how likely the side effect is, how severe it can be, and the potential consequences of not taking the drug. Let me give an example. Osteonecrosis of the jaw (ONJ) is a very rare condition in patients treated for osteoporosis with medications called bisphosphonates, such as Fosamax, Actonel, and Boniva. If it happens, it may be after a tooth extraction, when the bone in the jaw remains exposed for at least 6-8 weeks. It usually heals up eventually, and has not caused anyone to die. The risk is about the same as death by a lightning strike. On the other hand, the risk of fracture, which may result in loss of independence or death, is thousands of times higher if osteoporosis is not treated.

You must decide what is right for you, but please be sure you know all you need to know before making important healthcare decisions.

Mike Lewiecki

RISK AND BENEFIT

The question that is discussed in the columns to the left illustrates the concept of risk-benefit analysis. This is something we all do every day, usually without giving it a second thought. For example, you drive to the grocery store to pick up food for dinner. There is a risk of being in a serious car accident along the way, slipping and falling while walking down the aisle, injuring your back bending over to get something from the bottom shelf, or being mugged walking across the parking lot. However, in most cases you decide that the benefit of having food to eat is worth those risks, or "side effects," of doing the grocery shopping.

A risk-benefit analysis is something a doctor does before prescribing a medication. When the benefit of treating a medical conditions outweighs the risk of possible side-effects from medication, your doctor is likely to recommend taking the medication. Of course, you may have a different idea of what is an acceptable risk than your doctor.

The key factor is- be informed. Knowledge is power, especially in making decisions about your health and your life.



Support osteoporosis education in New Mexico. Help to reduce the burden of osteoporotic fractures. The 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.