

A CONTROLLED CASE STUDY WITH KRE-CELAZINE

Guideline  
FDA

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Study completed on September 4<sup>th</sup>, 2007

Performing Laboratory

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BRDL Study No.  
1251

**Introduction:**

The study was performed to assess the short-term benefits & side effects of Kre-Celazine in human beings when administered an oral dose at prescribe amounts and in conjunction with the topical cream at recommended doses. The study was intended to provide information on the potential health benefits and side effects of Kre-Celazine with respect to oral & topical exposure. Data from this study may serve as a basis for classification and/or labeling of the test article. Data also will serve as validated marketing research that presents the case for the effectiveness of Kre-Celazine. The study was performed by BioCeutical Research & Development Laboratory at 2376 Main Street, Room 14, Billings, Montana. The protocol was signed by the Study Director on July 1<sup>st</sup>, 2007. The study was initiated with test article administration on August 6<sup>th</sup>, 2007 and concluded with the final interview on September 4<sup>th</sup>, 2007.

**Procedure:**

Applications were taken to screen for Adult males or females that had arthritics, joint pain and inflammation. Subjects were chosen based on a tight criteria. In order to perform a good study, subjects needed to prove they had arthritics (and what type), joint pain and or chronic inflammation.

16 total applicants were chosen for the study. Any subject taking a prescription drug needed to get a permission slip signed off by their physician. During the course of the study, no changes were made by the administrator to the subjects diets, supplement program or drug intake. This was purely a Real Time Case Study to check the effectiveness and safety of Kre-Celazine in the live market place.

Below are the 4 week questioners that each subjects needed to fill out. This is what was used for monitoring their progress. Weekly interviews were conducted along with a final interview to summarize their 4 week study.

**Week 1**

Dose: Capsules: 2 capsules first thing in the A.M. (6:00 A.M. - 7:30 A.M.)

Cream: a dime's worth rubbed into hurting area or areas once per day.

Prior to starting the study, each subject was evaluated for a base line starting point using the below chart:

1 being the lowest and 5 being the highest (circle)  
 Scale: 1-good            2-not so good            3-bad            4-very bad            5-extremely bad

**Prior to starting:**

1). Pain Level	1	2	3	4	5
2). Mobility	1	2	3	4	5
3). Effects my daily routine	1	2	3	4	5
4). Pain at night	1	2	3	4	5
5). Energy Level	1	2	3	4	5
6). pH: _____					

The above chart was filled out at 7:00 A.M., 12:00 P.M. and 7:00 P.M. each day



**Summary:**

## Side Effects:

All test subjects reported No side effects.

## Effectiveness:

The following is the transcript from the final interview and data calculations from questioners:

September 4, 2007

**Subject 1:**

1). What is your main area of pain?

Joint pain, hands, hips and lower back. Subject has Hashimoto disease, which causes swelling of the hands, and is very painful.

2). What did the product do for you?

Not a significant difference than using Kre-Alkalyn. Subject has been using Kre-Alkalyn for several months. (Kre-Alkalyn is one of the components of Kre-Celazine)

3). Did it work better, the same or less than anything else you have tried?

The same because I have been using kre-alkalyn. Kre-Alkalyn has given me tremendous relief from my pain and has caused the swelling to go down in my hands. Did not see much of a change (since the Kre-Alkalyn has been doing so well) when subject started the study using Kre-Celazine. But data from questioner showed a 220% increase in benefits over base line start up.

No Side Effects were reported or observed.

**Subject 2**

1). What is your main area of pain?

Shoulders. Joint pain and hurts all the time.

2). What did the product do for you?

Helped with mobility. I have had a terrible time with moving my head and shoulders, but once I started taking the test product my mobility increased 10 fold.

3). Did it work better, the same or less than anything else you have tried?

Over the counter pain medicine seems to help me more with the pain, but they do nothing for the mobility. The test product did what my over the counter pain medicine could never do. It increased my mobility to were I could actually live a normal life. It did help somewhat with the pain, but that was hard to say since I use over the counter meds everyday. Subject did get some good pain relief from the lotion and it helped subject to relax at night.

No Side Effects were reported or observed.

### **Subject 3**

1). What is your main area of pain?

Knee's were worst with some lower back. Subject was diagnosed with arthritics in both knees along with a lot of swelling. Also has inflammation and swelling of the hands.

2). What did the product do for you?

My legs swell up and the pain is so bad it makes my leg and calf area unbearable. The pain is so bad that my calves get knotted up like a rock. The product took the inflammation & pain away and subjects calves did not lump as much. It helped with both knees. The pain was much less and she could walk well. After week one of study, subjects hands have not hurt and did not swell as much. The pain was less than normal and very bearable. It also helped with weather change problems that causes pain. These weather changes did not effect the pain like it usually does. Subject believes the inflammation has subsided and so does her Doctor.

3). Did it work better, the same or less than anything else you have tried?

I have tried one of the more popular prescription drugs and it really did not do anything for me. Well it did do something, all the side effects they claim really do happen. The product I used in the study helped more than the drug. No side effects. The test product also helped more for pain than the prescription drug I used. I also use Ibuprofen and the test product worked as well for pain. I quit the ibuprofen. I also use naproxen under a popular over the counter drug name. The test product worked as well as that also. I guess in summary, I really liked the test product and felt it worked better than any other drug I have ever used. Really liked the product and thought it worked better than anything else she has tried. Inflammation disappeared.

No Side Effects were reported or observed.

### **Subject 4**

1). What is your main area of pain?

Pain in knuckles on both hands

2). What did the product do for you?

It took away 90% of the pain and swelling in both hands and knuckles. It only took about 1 week to week and ½ to kick in . The test product really worked well for this subject.

3). Did it work better, the same or less than anything else you have tried?

The test product worked better then any over the counter arthritic pain reliever or any of the popular prescription arthritic drugs subject has tried. Really liked it and said "This product was quite amazing".

The test product completely took away the pain in subject hands and knuckles and did it better than any other drug subject has ever tried. The prescription drugs came with a price, multiply side effects. Subject felt the inflammation had disappeared.

No Side Effects were reported or observed.

## **Subject 5**

1). What is your main area of pain?

All over. Doctors have not figured out why subject has pain everywhere. Sometimes in the hands, sometimes in the back, sometimes in the legs, but all over at one time or another.

2). What did the product do for you?

Subject noticed instant relief with the cream. The caps she did not notice as much, but did notice some relief.

3). Did it work better, the same or less than anything else you have tried?

Subject has used arthritic drugs, but it took several months of loading before any effects were noticed. The drugs worked better only because subject was on them for several months before she noticed results. With the drugs nothing was ever noticed in the first 30 days. Subject got great relief from the cream and some relief from the caps. Actually, more in the first 30 days than from the drug therapy.

Subject thought the cream worked better than any other pain or arthritic cream she has ever tried. Felt the caps were working, but needed more time for it to kick in.

Subject would have mornings were it was difficult to move, but the cream was applied, subject put the cane back in the closet and was able to go on with the day. Cream really helped this subject.

No Side Effects were reported or observed.

## **Subject 6**

1). What is your main area of pain?

L5 in the back. Have arthritics in it.

2). What did the product do for you?

Took a lot of tension out of it. Subject has surgery coming up to take out the hardware that was put in for pain.

3). Did it work better, the same, or less than anything else you have tried?

This test product worked better than anything else I have ever tried. It took about 3 weeks to kick in. Has a lot of chronic pain and the test product really helped to relieve it. Test product is working better than the prescription pain pills he is taking. Before study, he had to take a high dose of his pain medication. During the study, subject cut back on the pain meds by 60%. Subject felt in time this cut back could become 100%.

No Side Effects were reported or observed.

## **Subject 7**

1). What is your main area of pain?

Leg and ankle pain due to a injury. Chronic Inflammation.

2). What did the product do for you?

Took away the pain. Four per day worked best. Did not have to take ibuprofen. Had some teeth work done during the study and the test product caused her teeth and gums to heal very quickly and subject did not have to take the prescribed pain medication.

3). Did it work better, the same or less than anything else you have tried?

Better. Worked better than any of the over the counter pain medication subject has tried. The test product really increased subjects relief from pain.

No Side Effects were reported or observed.

## **Subject 8**

1). What is your main area of pain?

Back and knees.

2). What did the product do for you?

Soothed it and took the pain away. The test product worked so well that I did not notice the pain at all during the day. It only took about 3 or 4 days to kick in.

3). Did it work better, the same or less than anything else you have tried?

Works better than anything else subject has tried. Had more energy and no pain.

Subject had an abscess tooth before starting the study. Test Product completely healed the inflammation and it healed up by end of study. The tooth was removed due to the fact it was almost dead. The DDR noticed that when the tooth was extracted how quick it clotted. The Doctor was also impressed on how quickly it healed, after the followup visit. Also, Subject's teeth & gums were more healthy.

No Side Effects were reported or observed.

## **Subject 9**

1). What is your main area of pain?

Lower back

2). What did the product do for you?

The higher dose of 4 caps is where I noticed a big difference. I have the most pain at night and the test product gave me great relief. It completely took the pain away. Subject still had some aches, but nothing like it was before starting product.

3). Did it work better, the same or less than anything else you have tried?

Better. Subject has tried a lot of things, MSM, glucosamine, etc and this product really did relieve the pain. The test product got the subject to a point that if that was the best it could do subject could live with it. Over all very impressed with what it did. No pain is very good, since subject has had so much over the years.

No Side Effects were reported or observed.

### **Subject 10**

1). What is your main area of pain?

Feet and back

2). What did the product do for you?

Nothing more than any other over the counter drug or prescription

3). Did it work better, the same or less than anything else you have tried?

It worked the same as anything else subject has tried. Subject has tried every prescription drug and over the counter drug known to man and none of them worked. But, test product had no side effects were the other drugs had adverse effects on him and data from subject's survey showed an over all increase in benefits by 60%.

No Side Effects were reported or observed.

### **Subject 11**

1). What is your main area of pain?

Left Knee

2). What did the product do for you?

It took about two weeks to kick in. It really worked on the knees.

3). Did it work better, the same or less than anything else you have tried?

The test product has worked as well as any of the prescription medication subject has used for arthritic pain and inflammation. Test product worked way better than any of the other over the counter drugs your doctor tells you to get, including supplements like glucosamine.

No Side Effects were reported or observed.

### **Subject 12**

1). What is your main area of pain?

Shoulder & Knee

2). What did the product do for you?

Made it easier to move and stiffness that is experience in the morning disappeared.

3). Did it work better, the same or less than anything else you have tried?

Better than anything else because the other joint pain medication the subject used quit working after a wee, where as the test product kept working the full 30 days. No pain and ease of mobility is what was experienced. Really got a lot of benefit from this study

No Side Effects were reported or observed.

**Conclusion:**

A). 12 out of 12 subjects all reported some to significant benefits from taking the test product over conventional prescription and over the counter arthritic & pain drugs. 12 out of 12 subjects all reported significant benefits over various health store products such as glucosamine & MSM. This is a success rate of 100%.

B). Zero side effects were reported and observed in 12 out of 12 test subjects. This is a success rate of 100%.

C). The following is the calculated data from the study. The categories used to measure the success rate were Pain Level, Mobility, Effects on my daily routine, Pain at night & Energy levels:

**Results:**

Pain level	Starting 41	Ending 22 or an average of 186.364% decrease in pain
Mobility	Starting 37	Ending 24 or an average of 154.167 % increase in mobility
Effects my daily routine	Starting 41	Ending 24 or an average of 170.833% increase in being able to due things more easily during the day
Pain at night	Starting 40	Ending 23 or an average of 173.913% decrease in pain at night
Energy level	Starting 34	Ending 21 or an average of 161.905% increase in energy.

**Over all Results:**

*Total score was added together and divided by 5 to obtain number averages*

Subject 12	Starting 3.6	Ending 1.0 or an average benefit increase of 360%
Subject 11	Starting 1.8	Ending 1.6 or an average benefit increase of 13%
Subject 10	Starting 3.2	Ending 2.0 or an average benefit increase of 60%
Subject 9	Starting 2.0	Ending 1.8 or an average benefit increase of 11.5%
Subject 8	Starting 3.4	Ending 1.0 or an average benefit increase of 340%
Subject 7	Starting 3.0	Ending 1.8 or an average benefit increase of 67%
Subject 6	Starting 4.4	Ending 2.2 or an average benefit increase of 100%
Subject 5	Starting 4.0	Ending 3.6 or an average benefit increase of 11.2%
Subject 4	Starting 2.8	Ending 1.8 or an average benefit increase of 55.5%
Subject 3	Starting 4.2	Ending 1.0 or an average benefit increase of 420%
Subject 2	Starting 4.0	Ending 4.0 or an average benefit increase of 0%
Subject 1	Starting 2.2	Ending 1.0 or an average benefit increase of 220%

12 subject average                      Starting 3.217 Ending 2.650 or an average benefit increase of 121.396%

**Conclusion:**

This study proved that Kre-Celazine was side effect free. This study also proved that Kre-Celazine decreased pain during the day and at night, along with increasing mobility, daily routines and energy levels. An average benefit increase showed a substantial 121.396%.

**Final Conclusion:**

According to this study, Kre-Celazine works as well or better than prescription and over the counter drugs for arthritics. Kre-Celazine is completely side effect free compared to the many side effects experienced from popular prescription and over the counter drugs for arthritics and pain.

According to this study, Kre-Celazine works better than popular health store products such as glucosamine and msm.

According to this study, Kre-Celazine is side effect free.