



Prezacor® Products Energezics® Technology

Prezacor® products – with ENERGEZICS® technology – are based on a USA patent-pending technology and formulation. From its many years of research and development, and from its proven clinical success, the Prezacor scientists have created a thin, flexible patch for the management of discomfort.

This unique skin-friendly patch, named the Energeze® Patch, accepts an electrical charge, acting as a stable classic semiconductor, inductor and energy-storing capacitor. The Energeze Patch holds its charge for a significant period of time, and



then releases its charge at a lower frequency than the original, charging electrical field. After the Energeze Patch absorbs the surface energy of the body where the patch is placed, it then modulates the stored energy and discharges it back to the site of application with a uniform, lower intensity, lower frequency energy. The Prezacor scientists believe that the released lower intensity, lower frequency energy acts to decrease the discomfort being experienced.

A rigorous clinical trial of the first ENERGEZICS product prototype demonstrated a greater than 70% response rate for reduction or elimination of pain in people with chronic lower back pain. Qualitative feedback from Prezacor users suggest that the product is effective for acute musculo-skeletal and neurogenic pain from a variety of causes. Additionally, data show that Prezacor products can be used safely daily and over prolonged periods of time.

Although its exact mechanism of action is unknown, the Prezacor compound may modify the spontaneous firing frequency of the nerve cell fibers that have become more sensitive in acute and chronic pain syndromes, thereby quieting the sensation of pain:

- The frequency of the energy absorption of the Energeze Patch is within the same range as the frequency of firing nerve cells that sense pain.
- Other researchers have found that the smallest applied electric field to which large molecules in cell membranes may respond is about two-thousandths of a volt per inch, which is lower than the intensity produced by the Energeze Patch. In some circumstances, scientific literature reports that energy fields at a much lower level of intensity than the Prezacor patch may be able to cause effects on nerve cell membranes and fibers.
- Furthermore, laboratory performance testing by our scientists has shown that the Prezacor Energezics technology modulates higher voltage inputs to a much lower, uniform output, with lower frequency.
- It is believed that the lower frequency release of the absorbed electrical field by the Energeze Patch results in a decrease in discomfort by either directly interfering with nerve signal transmission, or activating the nervous system (autonomic nervous system) associated with calming, or pleasurable, sensations. The intensity and frequency response of the Energeze Patch output supports this hypothesis.

Future clinical trials by Prezacor plan to directly measure the surface electrical fields, and note the alterations to neural output when the Energeze Patch is in place. Clinical evidence, using rigorous testing protocols, will also continue in order to verify the efficacy of the Energeze Patch.

Cost of Pain to Individuals and Companies

Pain relief is expensive. The annual cost to individuals, insurance companies and Medicare has been estimated to be as much as \$319 billion. One study reported in the *Journal of Pain* stated that individuals with moderate pain paid \$4,475 per year more for health care costs than individuals without pain. Patients with severe pain paid an additional \$3,210. Yet treatment is often ineffective since 57% of all adults report chronic or recurrent pain annually.

The impact of pain on business has also been estimated by a number of sources. The American Academy of Pain Medicine (AAPM) estimates that the annual cost to businesses for lost productivity is \$297.4 - \$335.5 billion. This is not only for sick days, but also for reduced productivity by employees who do come to work even though they hurt. AAPM reports that back pain alone in workers ages 45 to 60 costs employers \$7.4 billion/year.

The Pain Responses and Hypothesized Mechanism of Action

Despite years' of research, the mechanisms underlying pain are still not well understood. The receptors in skin and organs which detect noxious stimuli that the brain identifies as "pain" are varied. Molecular mechanisms in these same receptors can also distinguish among temperature, pressure and chemicals. Several kinds of nerve fibers (A fibers such as the A-beta fibers (A β), A-delta fibers (A δ), and the C fibers) couple with these receptors to transmit "messages" in the form of bioelectrical impulses to the spinal column and then to the brain. The intensity of the impulse transmitted is proportional to the breadth and strength of the noxious stimulus. Acute pain is perceived differently than chronic pain, and chronic pain may be real or a misinterpretation by the brain. Additionally, some patients' brains can "identify" the gentlest touch as being extremely painful since for some unknown reason the whole pain-sensing function has been seriously over-sensitized. Yet, if a patient is experiencing pain, treatment is necessary, even though determining the exact cause of pain may be difficult or even impossible.

The Energeze patch is applied directly over a pain site and is unique for its ability to employ the body's own energy to alleviate pain. Weak, non-ionizing electrical or electromagnetic fields have been clinically shown to exert a wide range of beneficial clinical effects within orthopedics, sports and physical medicine, plastic surgery, and chronic wound care. One such technology which is widely employed for pain treatment is transcutaneous electrical nerve stimulation (TENS) devices. TENS uses electric current produced by a portable device to stimulate the nerves. TENS has been in clinical use since the late 70's, and clinical data have been reported for numerous TENS devices. Like the Prezacor Energeze Patch, the exact mechanism of TENS has been hypothesized but is unknown. However, it is important to realize that both technologies use electrical stimulation at the site of pain, but with different intensities and potentially targeting different mechanisms.

The A β fibers appear to be stimulated at a relatively high rate (in the order of 90 - 130 Hz), and numerous devices, including TENS, target this frequency for pain relief. An alternative approach has been suggested in the literature, which is to stimulate the A delta (A δ) fibers which respond preferentially to a much lower rate of stimulation (in the order of 2 - 5 Hz). It is known that stimulation of the A δ fibers will activate the opioid mechanisms, and provide pain relief by causing the release of an endogenous opiate (enkephalin) in the spinal cord which will reduce the activation of the noxious sensory pathways. Considering the low frequency output of the Energeze Patch, this later mechanism is the most likely path that would explain the clinical efficacy of the Prezacor technology.

The Uniqueness of Prezacor

Inputting electrical energy at a pain site may relieve pain. TENS, while shown in some clinical studies to have pain reduction effects, has the disadvantage of needing an external electrical source for the voltage it releases, whereas Prezacor's Energezics technology does not. Also, unlike Prezacor's Energezics technology, TENS does not use or modulate the body's own energy to relieve pain. This difference may be important since each individual generates their own specific energy. It is

the specific individual's energy modulated to a lower and more uniform voltage level that Prezacor's Energezics technology employs. Further, whether it uses a battery pack or plugs into an outlet, TENS equipment isn't nearly as portable as an Energeze patch. And, while TENS equipment can be purchased for home use, it is costly. The Energeze patch is relatively inexpensive. It is the overall proven clinical effectiveness of the Prezacor technology and its hypothesized mechanism of action resulting from the modulation of a patient's own bioelectric energy that makes the Energeze Patch an extremely valuable product for the over-the-counter pain relief market.



References

1. John Gilly, PhD, Gary A.Karpf, MD, Robin R. Karpf, MD, Ian Livingstone, MD, Bruce Stouch, PhD, 2009 Study 001. *A Biphasic, Randomized, Double-Blind, Sham-Controlled, Parallel-Design Trial to Evaluate the Efficacy and Safety of the Prezacor® Back PAD-001 for the Attenuation or Relief of Chronic Low Back Pain of Mechano-Degenerative Origin*
2. Technical Report # DM709349. 2008. Prezacor Compound Samples. TUV Product Services, Inc. Danvers, MA.
3. Ian Livingstone, MD. 2012. Prezacor – White Paper on Pain. (Full paper available upon request to Prezacor – contact us at admin@prezacor.com)
4. R Morgan Griffin. The Cost of Pain. <http://www.medicinenet.com/script/main/art.asp?articlekey=50430&pf=3&page=1>
5. American Academy of Pain Medicine. The Cost of Pain to Business and Society Due to Ineffective Pain Care. http://www.painmed.org/patientcenter/cost_of_pain.aspx
6. John N Wood, Simon Beggs and Liam Drew. Sensing Damage. <http://www.wellcome.ac.uk/en/pain/microsite/science1.html>