

Prescribing Information

Indications and usage

Anodyne® Therapy is indicated to temporarily

- Increase local circulation
- Reduce pain, stiffness and muscle spasm

Warnings and Precautions

Anodyne® Therapy should not be used directly over an active malignancy or over the womb during pregnancy. There are no known drug interactions or side effects. As with other thermal modalities, there is a negligible risk of a superficial burn - approximately 3 adverse events are reported per estimated 1,000,000 professional treatments.¹⁷ If patients increase activity levels, blood sugar levels should be closely monitored. The use of Anodyne® Therapy alone does not cause hypoglycemia.

Treatment Information

Patients can be referred for treatment at a network of over 6,000 US based providers of Anodyne® Therapy including hospitals, home care agencies, physical therapy clinics and long term care facilities. If there is not a local provider listed on this brochure, contact **1-800-521-6664** to receive a local listing and additional referral materials. Treatments are typically included within a comprehensive plan of care administered three times per week, for an average of four to five weeks.

Continuity of Care After Discharge

For those with a chronic condition, symptomatic relief obtained from Anodyne® Therapy treatments generally decreases over time after the treatment is withdrawn. For these patients, ongoing relief can be obtained from either periodic additional treatment in a clinical setting or through self treatment with an Anodyne® home system. Ongoing treatment is typically not necessary for patients with an acute condition, however individual results may vary.



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References

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The US FDA has not reviewed, evaluated or approved the described uses discussed in these clinical references

Anodyne® Infrared Therapy

A New Treatment Approach for Patients with Pain

▶ Drug-free

▶ Non-invasive

▶ Effective

Introducing Anodyne® Infrared Therapy

The Anodyne® Therapy System is a FDA cleared, non-invasive medical device. This system emits monochromatic infrared light (MIRE™), providing an effective treatment for pain, poor circulation and muscle spasm caused by a range of factors including acute injuries, chemotherapy, diabetes and vascular disease.

Anodyne® Therapy provides significant symptomatic relief¹⁻⁶ throughout treatment while, due to its topical application, avoiding systemic side effects.

Healthcare professionals working in over 6,000 organizations use Anodyne® Therapy as an effective, non-invasive, treatment approach for their patients. These organizations include the US military, professional sports teams, homecare agencies and outpatient centers

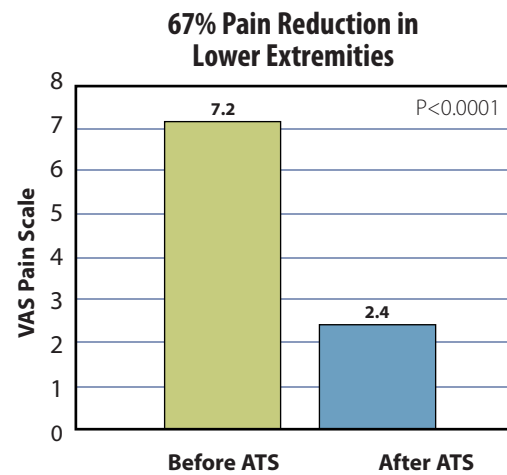


Clinically Proven Results 21 Peer Reviewed, Published Studies

Treatment with Anodyne® Therapy has the potential for both therapeutic and prophylactic utility, with positive results becoming evident after several treatments of 30-40 minutes duration.¹

18 studies (involving over 5,000 patients) have been published in peer reviewed journals noting significant objective improvements across various endpoints such as:

- 67% mean reduction in lower extremity pain²
- Pain medication elimination or reduction for 51% of subjects³
- 49% reduction in pain levels for subjects with horrible to excruciating pain (vas 8.5-10)⁴
- 91% of subjects sustained pain relief over 12 months of continuous use⁵
- 90% of subjects with muscle spasm experienced 'total relief' within 12 treatments⁶



Journal of Diabetes and its Complications 2006, March/April Vol 20, No.2 (n=2239)

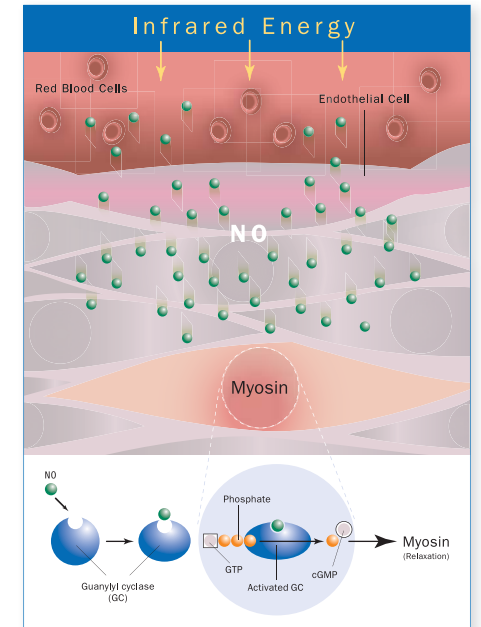
Studies consistently show that patients have a high treatment response with a minimal side effect profile, and that efficacy is sustained throughout treatment.

The Method of Action is Specific... Infrared Light Stimulates a Local Release of Nitric Oxide

Mainstream knowledge of infrared LED technology developed in response to experiments conducted by NASA for the healing of injuries in space.

The Anodyne® Therapy System emits light at 890 nm through super luminous LED's. This wavelength combined with a patented, direct contact design maximizes the absorption of the infrared light into the body.

This modality provides a way for clinicians to treat patients with poor circulation as the use of infrared light has been shown to temporarily increase blood flow, and trigger the local release of nitric oxide(NO).⁷⁻⁸



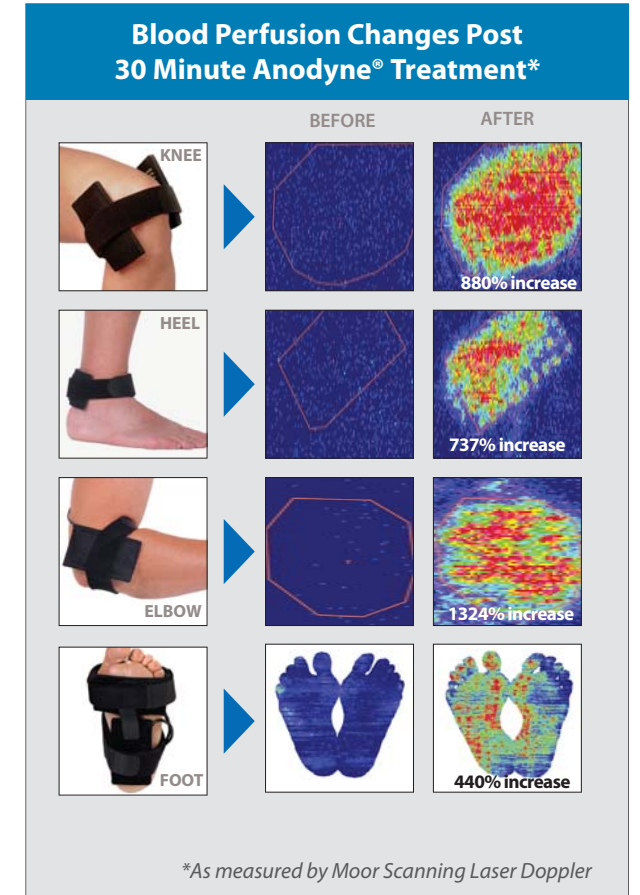
NO induces the synthesis of cyclic GMP by stimulation of guanylate cyclase leading to relaxation of myosin

Nitric Oxide has been linked with:

- Vasodilation⁹⁻¹⁰
- Reduction of pain¹¹
- Reduction in inflammation¹²
- Angiogenesis¹³
- Collagen synthesis¹⁴

NO is an important regulator and mediator of numerous processes in the nervous, immune and cardiovascular systems⁹⁻¹⁴, however, it is perhaps most well known for its role in vasodilation. When released, NO stimulates the endothelial lining of both arterial and venous blood vessels causing vasodilation.⁹⁻¹⁰

Simulating circulation and vasodilation without systemic side effects may be particularly significant for patients with diabetes and other vascular diseases. Research shows that these patients exhibit endothelial dysfunction, impaired nitric oxide metabolism and vascular responsiveness which possibly contribute to their experience of pain.¹⁵⁻¹⁶



*As measured by Moor Scanning Laser Doppler

