

ZERO

topical muscle relaxants exist on the market today

THE CHALLENGE



- ✦ G-forces trigger significant muscular spasm in Air Force pilots, undercutting combat readiness
- ✦ Rotary- and fixed-wing vibration compounds the problem; heavy helmets add further strain
- ✦ Root cause: muscle spasm and tightness. Requires significant rest for muscle to relax.

“Failure of muscles to relax is often the true root cause of spasm-related pain.”

Prescription Relaxants Fall Short

- ✦ Flexeril, Skelaxin, Robaxin, Norflex & Valium act via the brain — causing drowsiness & headaches

No OTC Product Relaxes Muscle

Product	Counter-irritant	Anti-inflammatory	Anesthetic	Muscle Relaxant
AleveX	✓	–	–	–
Bengay	✓	✓	–	–
Icy Hot	✓	✓	–	–
Voltaren	–	✓	–	–
Salonpas	–	–	–	–
PI-111	–	–	–	✓

No leading OTC topical product on the market today contains a muscle relaxant.

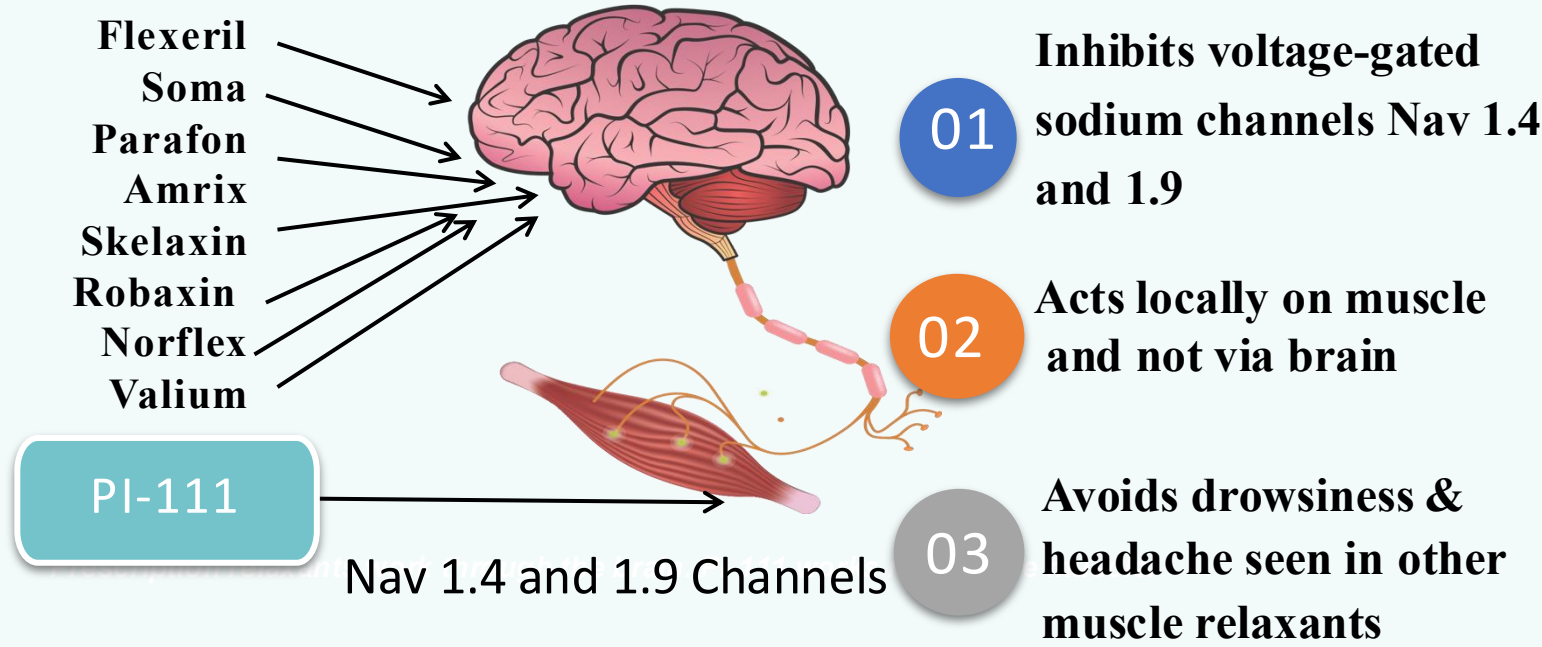
The Opportunity

A gap exists between prescription relaxants (effective, but sedating) and OTC topicals (safe, but not muscle-targeted). PI-111 is designed to fill that gap.

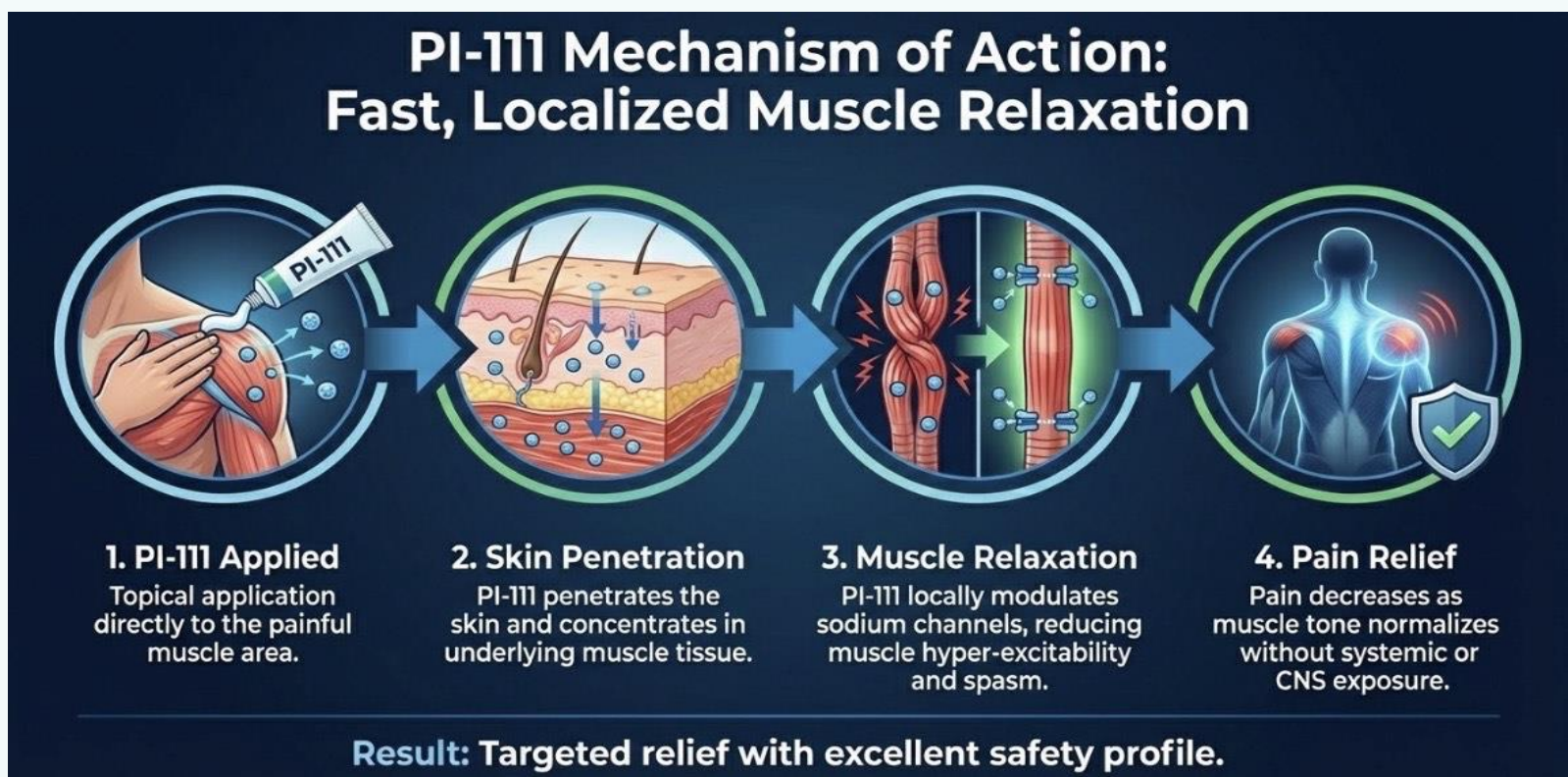
3.2×

greater reduction in motor activity vs. vehicle in rota-rod testing

MECHANISM OF ACTION



OUR SOLUTION



Backed by Pharmacology

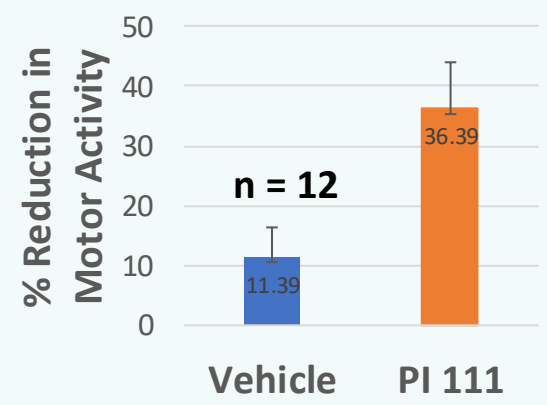
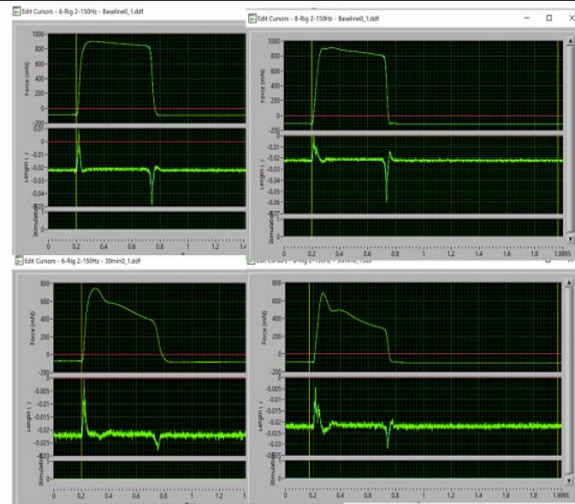
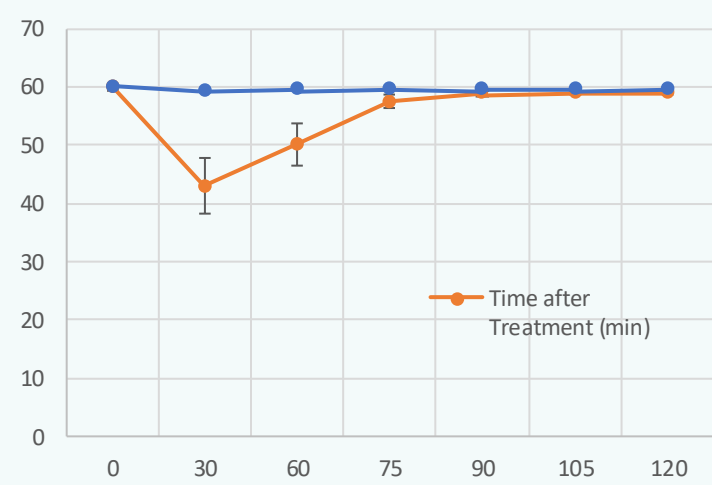
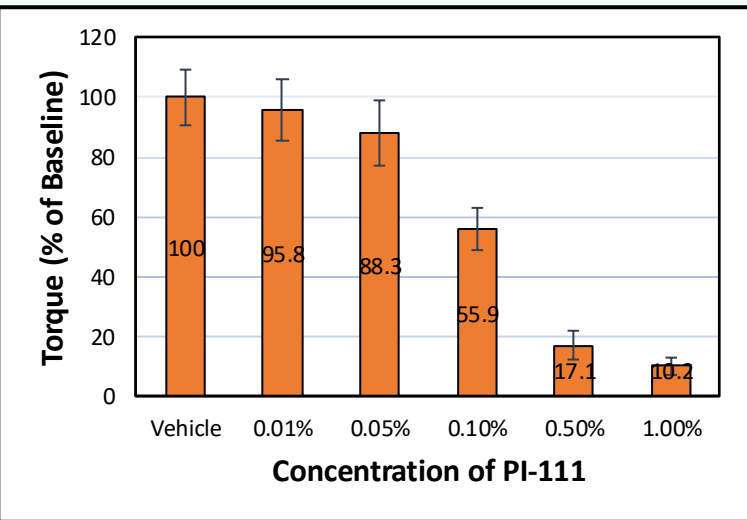
Grounded in non-GLP in vitro and in vivo pharmacology studies, with mechanism of action established across multiple experimental models.

NO CNS Involvement

Hence, no sedation or cognitive impairment — unlike prescription relaxants

VALIDATION DATA

- ✦ Muscle twitch experiment — in vivo
- ✦ Isolated muscle study — in vitro
- ✦ Rota rod study — in vivo
- ✦ Open field test — in vivo



In rat hindlimb studies, vehicle-treated muscle sustained tetanic contraction — topical 5% PI-111 suppressed the muscle's ability to maintain it.

Informal Human Evaluations

- ✦ Compared head-to-head with diclofenac gel and moisturizing lotion
- ✦ Torticollis patient
- ✦ Neuropraxia patient

2046

Patent protection for PI-111's dual mechanism

INTELLECTUAL PROPERTY

- 2032** Granted patent US 8,853,189 B2 — muscle-spasm inhibition, incl. combo with anti-inflammatories (e.g., diclofenac)
- 2043** Application filed Dec. 2023 — PI-111 + anesthetic agents
- 2043** Application filed Dec. 2023 — PI-111 + osmotic agents
- 2046** Application filed June 2026 — dual Nav 1.4/1.9 mechanism (relaxant + analgesic)

FDA grants 5 years of market exclusivity after approval.

BUILT FOR THE COCKPIT

Avoids Cockpit-Disqualifying Side Effects

Because PI-111 acts locally at the muscle rather than through the brain, it avoids the drowsiness and cognitive impairment that make CNS-acting relaxants unsuitable for pilots on flight status — keeping them mission-ready without compromising alertness.



DEVELOPMENT PATH & ASK

COMPLETED

Proof of principle, informal human studies, MOA established
~\$550K invested

FILE IND

Animal efficacy & tox studies, formulation finalization
\$2M · 1 year

SERIES A / B

Phase I/II then Phase III clinical trials
\$7M + \$15M · 3 yrs

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