

Topical Nifedipine for Raynaud Phenomenon

Market need

There is a need for a convenient and effective treatment for Raynaud Phenomenon (RP) that immediately addresses the main symptoms without significant side effects. In cases of secondary RP there is a need for treatment options that are not contraindicated by the primary disease or its treatment.

Our solution

A novel, topical formulation for immediate use, as needed. This formulation takes existing compounds which have already been pharmaceutically tested and stabilizes them in a convenient cream that can be applied to the affected area for fast relief. The main medicinal ingredient is nifedipine, a generic vasodilator that has historically been given orally because its photolability causes its effectiveness to decline dramatically when exposed to light.

Benefits of our approach

- Effectively and quickly delivers the active ingredient directly to the affected area, resulting in fast relief.
- Solves the problem of nifedipine's photolability, the main barrier to topical treatment with this compound.
- Increases likelihood of being used by patients as the formulation is convenient and non-greasy.
- Provides alternative or supplementary treatment to patients who currently address symptoms via lifestyle changes.
- Eliminates the main drawback of oral treatment by eliminating side effects.
- Expands treatment options for secondary RP, as the topical application of nifedipine is less likely to interact poorly with other diseases or medications.
- Based on known compounds combined into a convenient delivery mechanism that is safe and effective.
- From a drug development perspective, this IP-protected novel formulation of existing ingredients reduces time to market, as all ingredients are known compounds with extensive clinical histories.

Background

About Raynaud Phenomenon

Raynaud Phenomenon (RP) is a medical condition where spasms of arterioles cause reduced blood flow, which leads to numbness or pain primarily in the fingers, and can progress to skin sores or gangrene in extreme cases. The cause of primary RP is unknown; secondary RP is a significant problem in association with other diseases such as scleroderma and rheumatoid arthritis, in which ulcers become a problem. The condition affects approximately 3-5% of the population, primarily women, with onset between ages 15 and 30.

Current treatment options

The main approaches to management are based on lifestyle changes: avoidance of cold environments and reduction of stress. Active treatment includes systemic and local warming. Medical treatment is primarily based on oral medications intended to reduce the frequency and severity of attacks. The most common oral medication approach is vasodilators (calcium channel blockers), which increase blood flow. These have side effects such as headache, flushing and swelling in the ankles due to fluid accumulation. Furthermore, the benefits from oral medications are minor as they only slightly reduce frequency of attacks.

Topical formulations can be made by qualified compounding pharmacists but this must be done in a dark environment using special equipment. There are other topical compounds on the market, but they lack clinically proven effectiveness (e.g. nitroglycerin).

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Patents/applications (priority date May 2017): US granted patent 10,543,202 - "TOPICAL NIFEDIPINE FORMULATIONS AND USES THEREOF"; Canadian patent application 2,968,861 - "TOPICAL NIFEDIPINE FOR RAYNAUD'S PHENOMENON"

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