

Currently Participating Locations

- Baltimore, Maryland
- Boston, Massachusetts
- Dallas, Texas
- Fremont, California
- Gainesville, Florida
- Houston, Texas
- Indianapolis, Indiana
- Los Angeles, California
- Little Rock, Arkansas
- Lynchburg, Virginia
- Mayfield Heights, Ohio
- New Brighton, Minnesota
- New York City, New York
- Omaha, Nebraska
- Rochester, New York
- Rogers, Arkansas
- Salt Lake City, Utah
- Skokie, Illinois
- San Diego, California
- Sugarloaf, Pennsylvania
- Winston Salem, North Carolina

For a List of Site
Contact Information Visit
patients.nflectionrx.com



SCAN ME

ABOUT US

NFlection is dedicated to bringing patients a safe and effective non-surgical treatment for cutaneous neurofibromas in neurofibromatosis type 1 through the discovery and development of effective, targeted therapies for rare disorders driven by aberrant activation of the RAS pathway (RASopathies).

NFlection

THE R A P E U T I C S

Topical Gel Study for Adults with NF1 & cNFs

The purpose of this study is to test the safety and effectiveness of 2 concentrations of NFX-179 gel compared with placebo gel in reducing the appearance of cutaneous neurofibromas (cNFs) in patients with Neurofibromatosis Type 1 (NF1).



clinicaltrials.gov/ct2/show/NCT05005845

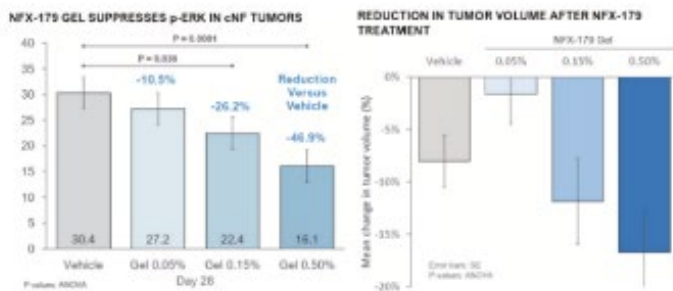
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About NFX-179 Topical Gel

NFX-179 Topical Gel is an investigational mitogen-activated protein kinase kinase (MEK) inhibitor. NFX-179 Topical Gel is a "soft" (metabolically labile) drug, which, when formulated as NFX-179 Gel for topical application, is designed to concentrate at the dermal site of action but degrade in systemic circulation, thereby potentially significantly reducing side effects compared to systemically available MEK inhibitors.

Previous Phase 2a Study Results

- NFX-179 gel (0.05%, 0.15%, and 0.5%) or vehicle was applied topically once daily to 5 target cNF tumors for 28 days and tumors were removed for p-ERK biomarker analysis at the end of the study
- 10 AEs reported in 8 patients, but none related to study drug: sleep apnea, lower leg edema, basal cell carcinoma, worse anxiety, COVID-19 (moderate); scalp hair loss, seasonal allergies, COVID-19, excision infection x2, menopause symptoms (mild)
- No acneiform rash or other side effects of oral MEK inhibitors observed
- No adverse events related to changes in clinical lab values or ECG findings
- **NFX-179 gel-related reduction in p-ERK in cNFs and a 47% reduction in the 0.5% NFX-179 Gel group compared with vehicle**
- **NFX-179 gel-related reduction in cNF volume and 17% mean reduction in 0.5% NFX-179 gel group compared to 8% in the vehicle group**



Key Criteria to Participate

- At least 18 years of age
- 10 cNFs (at least 1 on face and 9 on upper body) that are:
 - Face: length and width ≥ 5 mm and ≤ 14 mm, height is ≥ 2 mm
 - Body: length ≥ 7 mm to ≤ 14 mm, width ≥ 5 mm to ≤ 14 mm, height is ≥ 2 mm
 - Not within 1 centimeter cm of the orbital rim
 - Physician's Tumor Assessment grade ≥ 2
 - Discrete, dome shaped, not pedunculated
 - Not irritated, infected, or in repeat trauma area
- Negative pregnancy test for female patients of childbearing potential
- Not used within 30 days before treatment:
 - Corticosteroids
 - Retinoids,
 - 5% alpha-hydroxy acid
 - Fluorouracil
 - Imiquimod
- No energy-based or photodynamic therapy within 180 days
- No topical MEK or BRAF inhibitor treatment to Target cNF ever
- Not used systemic Retinoid therapy within 90 days
- Not used systemic MEK or BRAH inhibitor therapy within 180 days
- No history of hypersensitivity to study drug ingredients
- No known intercurrent illness or condition impairing participation
- Not participated in an investigational drug within 30 days

For More Study
Information:

