

# VITESSE Study: a Groundbreaking Clinical Trial for Children with Peanut Allergy



## What is VITESSE and Why Does it Matter?

VITESSE is a Phase 3 clinical study evaluating VIASKIN Peanut patch, an investigational treatment for children ages 4-7 living with peanut allergy. The study was designed to determine whether a daily patch can safely help children become less sensitive to accidental peanut exposure. Nearly 400,000 children in the U.S. ages 4-7

have a peanut allergy. Allergic reactions are unpredictable, and accidental exposures happen despite the best efforts to avoid them. There remains a real need for proactive approaches that not only reduce the risk and severity of allergic reactions but also address the barriers to care that exists with current therapies.

## About VITESSE

### 1 Who participated in VITESSE?

The study (NCT05741476) enrolled children 4 to 7 years of age diagnosed with peanut allergy. Participants were randomized 2:1 to receive either the peanut patch or a placebo.

### 2 How did the study work?

VITESSE was a randomized, double-blind, placebo-controlled phase 3 study. Trial participants applied the patch (either VIASKIN Peanut patch or placebo) daily for a period of 12 months.

### 3 What was the goal?

The primary endpoint was based on the difference in treatment responders in the active versus the placebo arms. A treatment responder was defined according to pre-specified changes in eliciting dose (ED, the amount of peanut protein that triggered a reaction) from baseline to Month 12. The study also assessed the safety of the patch, including adverse events, local site reactions and systemic allergic reactions.

## About VIASKIN® Peanut Patch

VIASKIN Peanut is a non-invasive investigational treatment designed specifically for young children with peanut allergy. This novel approach utilizes epicutaneous immunotherapy (EPIT) which seeks to re-educate the body's immune system by introducing allergen to the skin.



VIASKIN Peanut aims to reduce the risk and severity of allergic reactions and ultimately improve the lives of those with peanut allergy.

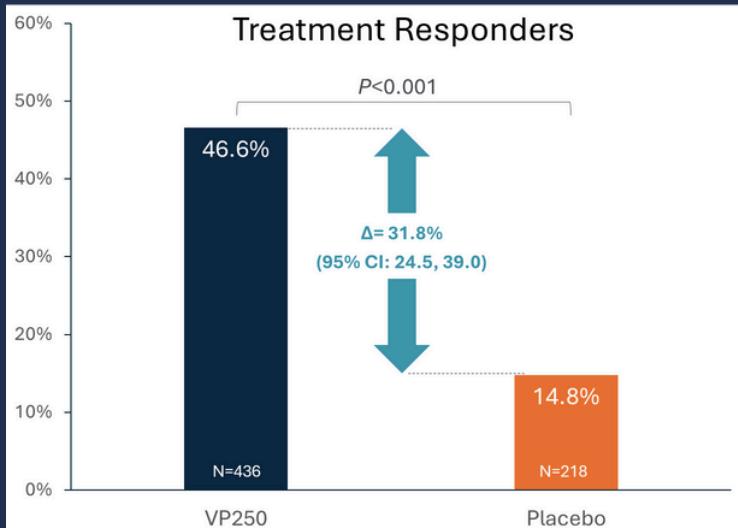
### 4 What were the results?

The VITESSE study found that the VIASKIN Peanut patch was successful at desensitizing children to peanut. Children in the active treatment arm could tolerate greater amounts of peanut compared with children on placebo. Most side effects were mainly mild-to-moderate localized skin reactions. Cases of treatment-related anaphylaxis were rare.

Please see Page 2 for more information on topline results.

## Topline Results of VITESSE

### Primary Endpoint



**In VITESSE, there were 3x more treatment responders on VIASKIN Peanut after only 1 year**

#### What is a responder?

Responders were defined as children with a baseline ED  $\leq 30$  mg who achieved an ED  $\geq 300$  mg of peanut protein at month 12, or children with a baseline ED = 100 mg who achieved an ED  $\geq 600$  mg of peanut protein at month 12

### Safety

**VITESSE safety results were consistent with the safety profile of the VIASKIN clinical program to date. The most common treatment-emergent adverse events (TEAEs) observed during the study were mild-to-moderate local skin reactions at the patch application site. Notably, there were no reports of treatment-related serious adverse events and treatment-related anaphylaxis was low at 0.5% (n=2). Compliance was high at 96.2%, suggesting the treatment was well tolerated by children in this study.**

### What's Next?

Eligible children who participated in VITESSE could enroll in the open-label extension study, where all participants receive VIASKIN Peanut for up to 3 years. This is to evaluate the long-term safety and efficacy of VIASKIN Peanut in this age group.

DBV plans to submit a Biologics License Application to the FDA in the first half of 2026.

### About the Sponsor

DBV is a biotechnology company committed to helping children with food allergies live safely. We are developing the VIASKIN patch, a non-invasive technology based on epicutaneous immunotherapy (EPIT), that re-educates the immune system through the skin. Our goal is to offer families a safe, effective, and accessible treatment option to help protect them from accidental exposure reactions.

Follow us on Facebook, Instagram, Facebook, and X (formerly Twitter).

VIASKIN is a registered trademark of DBV Technologies.

As of December 2025, VIASKIN Peanut patch is an investigational product not yet approved by the U.S. Food and Drug Administration.

