amuse

FOR HEALTHCARE PROFESSIONALS ONLY

Clinical Overview · Not for patient distribution

CLINICAL OVERVIEW

Early Allergen Introduction — What You Need to Know

A quick-reference summary for providers. Full evidence, specs, and safety detail begin on page 2.

WHY EARLY INTRODUCTION MATTERS

- **81% reduction** in peanut allergy development vs. avoidance
  LEAP, 2015 · high-risk infants
- **NNT 7–14** in eczema subgroup vs. NNT 63 general population
  PreventADALL, 2022
- Real-world adherence remains low — only **~45%**of infants introduced to peanut by 6 months despite guidelines
  AAAAI/ACAAI 2024 guidance

WHAT PROVIDERS SHOULD DO

- Introduce allergens at 2**–6 months** — earlier within window associated with better outcomes
  AAAAI/ACAAI 2024 guidance
- Prioritize **consistent daily exposure** — irregular exposure reduces effectiveness
  EAT, 2016; EarlyNuts, 2024
- **Stratify by eczema risk**— refer moderate-severe eczema infants to allergist before initiation
  AAAAI/ACAAI 2024 guidance

WHERE AMUSE FITS

- **Daily, consistent format**— 3 pumps once daily, designed to support the adherence consistency trials show matters
- **Complements whole food introduction** — not a replacement; whole foods provide nutrition and feeding skill development
- **Dietary supplement** — not FDA-approved, not a drug or medical treatment; no rx required

Important: All statistics above are findings from referenced published trials — not claims about Amuse. Amuse is a dietary supplement (DSHEA-regulated). It has not been evaluated by the FDA and is not intended to diagnose, treat, cure, or prevent any disease. Clinical data cited herein describes outcomes from study populations. Full regulatory disclosure on final page.

amuse

FOR HEALTHCARE PROFESSIONALS ONLY

Clinical Overview · Not for patient distribution

1. Product Overview

Amuse is a once-daily oral dietary supplement providing consistent exposure to six common food allergens during early infancy. Developed by Dr. Brynn Everist, Mayo Clinic-trained allergist and immunologist.

CATEGORY
Dietary supplement (DSHEA). Not FDA-approved. Not a drug or medical treatment.

ALLERGENS
Peanut,. cashew, walnut, milk, egg, sesame

DOSE
3 pumps (0.42 mL total) orally, once daily

START AGE
From 2 months, aligned with trial introduction windows

QUALITY
Third-party tested, cGMP-compliant supplement manufacturing facility

AVAILABILITY
Direct-to-consumer monthly subscription, no prescription required

2. Evidence Base

All statistics and findings below are from the referenced published trials. They are not claims about Amuse.

Study	Population	Timing	Key Finding	Journal
LEAP (2015)	High-risk; eczema/egg allergy (n=640)	4-11 mo	81% reduction in peanut allergy vs. avoidance group	NEJM 2015
EAT (2016)	General population; breastfed (n=1,303)	3 mo	Significant reduction per-protocol; whole food adherence challenging in ITT arm	NEJM 2016
PreventADALL (2022)	General population (n=2,397)	3 mo	Food allergy 0.9% vs. 2.3% control at 36 months; NNT=63 (general), NNT=7–14 (eczema subgroup)	Lancet 2022
EarlyNuts (2024)	Post-guideline cohort (n=1,420)	Varied	11.3% prevalence despite guidelines; only 45% introduced peanut by 6 mo; persistent risk: early eczema, Asian ancestry, early antibiotics	JACI Pract. 2024

LEAP 2015- HIGH-RISK POP.
81%
Reduction vs. avoidance in this trial

PREVENTADALL 2022 GENERAL POP.
NNT 63
To prevent one case at 36 months

PREVENTADALL 2022 ECZEMA SUBGROUP
NNT 7-14
Moderate-severe eczema subgroup

EARLYNUTS 2024 REAL-WORLD
~45%
Reduction vs. avoidance in this trial

AAAAI/ACAAI 2024 Guidance

Current consensus supports early introduction for most infants including those with mild-moderate eczema or family history. For severe eczema or suspected sensitization, allergist evaluation before introduction is recommended. Duration data suggest 2–3 years of consistent exposure for highest likelihood of sustained esponse.

3. Biological Mechanisms Under Study

This section summarizes mechanisms discussed in the published literature — not a description of how Amuse works. Not evaluated by the FDA.

Dual Allergen Exposure Hypothesis

Early oral exposure may support tolerance development; skin exposure through a compromised barrier (eczema) may contribute to sensitization. Route and timing of first exposure appear to influence immune response.

> *Lack G. J Allergy Clin Immunol. 2008 and subsequent literature.*

Mucosal Immune Environment

Oral mucosal tissue contains dendritic cells that may play a role in immune response to early food protein contact. Clinical significance in dietary supplement contexts differs from pharmaceutical SLIT trials and is not established.

> *Research context only — not a claim about Amuse.*

Regulatory T Cell Response

Some early introduction studies have examined whether consistent early exposure may support allergen-specific Treg development. Findings from clinical immunotherapy trials in already-allergic populations cannot be generalized to healthy infant supplement contexts.

> *Research context only — not a claim about Amuse.*

Duration of Exposure

AAAAI/ACAAI 2024 guidance reflects trial data suggesting 2–3 years of exposure may be associated with higher probability of sustained immune response. This is a clinical guideline interpretation, not a product recommendation from Amuse.

> *Fleischer DM et al. JACI Pract. 2021;9:22–43 and AAAAI/ACAAI 2024 update.*

4. Suggested Use & Safety Considerations

Not a clinical protocol. Informed by published trial data and AAAAI/ACAAI guidance. Providers should use independent clinical judgment for individual patients.

POTENTIALLY APPROPRIATE FOR

- Healthy general population infants
- Mild eczema where introduction is being considered
- Family history of food allergy — discuss risk/benefit
- Families where daily adherence to whole foods is challenging

⚠ CONSULT ALLERGIST FIRST

Not for use without allergist evaluation in these situations

- Diagnosed/suspected IgE-mediated food allergy
- History of anaphylaxis to any food
- Known or suspected FPIES
- Moderate-severe eczema, especially onset <6 months
- Acute systemic illness or compromised immune system

1 Timing

2–6 months of age after breastfeeding established; earlier within this window associated with better outcomes (PreventADALL).

2 Dosing

3 pumps (0.14 mL) orally once daily. Consistent daily use is key.

3 Duration

AAAAI/ACAAI data suggest 2–3 years for highest likelihood of sustained response. Providers should advise individually.

4 First dose

Higher-risk infants (moderate-severe eczema): consider supervised first dose. General population: home initiation appropriate per AAAAI/ACAAI guidance.

5 Monitoring

Counsel families on allergic reaction signs; seek immediate care if severe symptoms occur. Routine well-child schedule appropriate for most.

Allergic Reaction Counseling Points

Mild / Moderate — monitor and contact provider	Severe / Emergency — call 911 immediately
Hives, skin redness, mild lip/tongue swelling, runny nose, vomiting, diarrhea	Difficulty breathing, stridor, throat tightening, pale/blue skin, limpness, altered consciousness, significant tongue/throat swelling

5. References

1. Du Toit G, et al. Randomized trial of peanut consumption in infants at risk for peanut allergy (LEAP). N Engl J Med. 2015;372:803–813.

2. Perkin MR, et al. Randomized trial of introduction of allergenic foods in breast-fed infants (EAT). N Engl J Med. 2016;374:1733–1743.

3. Skjerven HO, et al. Early food intervention and skin emollients to prevent food allergy (PreventADALL). Lancet. 2022;399:2398–2411.

4. Soriano VX, et al. Prevalence and determinants of food allergy in the era of early allergen introduction (EarlyNuts). J Allergy Clin Immunol Pract. 2024 [In Press].

5. Fleischer DM, et al. Consensus approach to primary prevention of food allergy (AAAAI/ACAAI/CSACI). J Allergy Clin Immunol Pract. 2021;9:22–43.

6. Iglesia EG, et al. Health promotion of early and sustained allergenic food introduction. J Allergy Clin Immunol Pract. 2024;12(7).

7. Lack G. Epidemiologic risks for food allergy (dual allergen exposure hypothesis). J Allergy Clin Immunol. 2008;121:1331–1336.

REGULATORY & LEGAL DISCLOSURE

*** These statements have not been evaluated by the Food and Drug Administration. Amuse is not intended to diagnose, treat, cure, or prevent any disease.**

Amuse is a dietary supplement regulated under DSHEA (21 CFR Part 111), not a drug, biologic, or medical device. It has not been FDA-evaluated for safety or efficacy.

Clinical data in this document are findings from referenced peer-reviewed trials and are not claims about Amuse. Early introduction research used whole food allergens in clinical trial settings; findings may not generalize to dietary supplement contexts.

For licensed healthcare providers only. Not for patient distribution. Providers should use independent clinical judgment for individual patients.