

"Off-Label" Therapy Consent for Sublingual Immunotherapy



The term "off-label" means that the therapy will be used in a way not listed on the official labeling of the product and not specifically FDA-approved for use in this manner. Off-label treatment is very common in medicine. Being "off-label" does not mean the medication is not safe to use; it simply means the FDA has not yet formally approved the method of treatment for your condition. An allergy drop (sublingual immunotherapy) consists of allergy extract currently FDA-approved for injection but not for administration under the tongue. Sublingual allergy tablets are only FDA approved for single allergen treatment.

An off-label medication may be used for:

- A disease other than the one for which it was approved
- A different dose, duration, or frequency than stated on the label
- Treatment for a child when the medication is only approved for adults

Alternative treatment options include avoidance of the substances to which you are allergic, medication therapy, and/or allergy injections (subcutaneous immunotherapy).

There are risks associated with sublingual allergy treatment. The most common are minor local side effects such as itching or swelling in the mouth. Severe allergic reactions (anaphylaxis) are possible, although rare. All patients on sublingual immunotherapy will be prescribed self-injectable epinephrine (EpiPen, Auvi-Q, etc.).

The expected benefits from this form of treatment include:

- Reducing allergy and asthma symptoms
- Improving your allergen tolerance
- Helping your allergies go into remission

I have received and understand the above information and am aware of alternative treatments as well as risks and benefits of sublingual immunotherapy. My questions have been answered and I wish to proceed with this off-label therapy.

Patient Name

DOB

Signature of Patient or Responsible Party

Date

Witness

Date