

Capitol Ear, Nose, and Throat

4600 Lake Boone Trail, Suite 100, Raleigh, NC 27607 TEL 919-787-1374 ■ www.capitolent.net

_	INSTRUCTIONS FOR SUBLINGUAL IMMUNOTHERAPY	
	TRICTIONAR LAND STIDLIRATION TRANSITRATION DELICATIV	

	Page 1
Name	PATIENT:
Address	No. / DOB:
Address	DATE:

You are currently under treatment for allergic respiratory disease (ICD-9 Code 477.9 and/or 493.00). You have requested that your sublingual allergen immunotherapy treatment be administered outside of our clinic. This treatment packet includes information that will be important for you as you administer the prescription allergy drops. Your treatment packet includes the following items:

GENERAL INFORMATION FOR THE ADMINISTRATION OF IMMUNOTHERAPY - SLIT (PAGE 2):

Please read this section carefully prior to beginning immunotherapy. You will find practical guidelines for taking the oral drops, including advice for adjustment of the dose following minor adverse reactions, as well as following an extensive time interval between doses. This section also includes information concerning management of local and systemic reactions.

DOSAGE PROTOCOL & TREATMENT RECORD - SLIT (PAGES 3 – 7):

Here you will find the prescribed dosage schedule for your treatment. Please record all doses on this Treatment Record. This 4-page record will need to be returned to our office for review prior to renewal of the allergen vaccine prescription.

RENEWAL PROTOCOL FOR ALLERGEN VACCINE PRESCRIPTION - SLIT:

As you record your daily doses, you will come to a notation reminding you to arrange for renewal of your prescription vials. In order to renew our vials, please contact our office at 919-787-1374 and ask to speak to the allergy department. You will be asked to provide your treatment record and payment prior to renewing your vials. You may be instructed to make a follow up appointment with your Capitol ENT physicians. Your vials can be picked up at our office or mailed to you for your convenience.

Questions?	Please call us at 919-787-1374.

GENERAL INFORMATION FOR THE ADMINISTRATION OF IMMUNOTHERAPY - SLIT

PAGE 2

■ PRACTICAL INFORMATION REGARDING ADMINISTRATION OF ALLERGY DROPS:

ADMINISTRATION OF SUBLINGUAL DROPS:

- 1. Dosing should be done at the same time each day, preferably in the morning.
- 2. Record all doses on the attached Treatment Record (Pages 3, 4, and 5).
- 3. Record the date of dosing.
- 4. Prior to dosing, review the Health Screen and, if applicable, check your Peak Flow reading. If the Health Screen questions are answered "no" and if your Peak Flow is in the green zone, check the Health Screen box and proceed with dosing. If not, call our office and ask to speak with one of the nurses.
- 5. Drops should be placed under the tongue and held there for two minutes, then swallowed. For multiple vial sets, drops from each vial may be added together under the tongue all at once. If local mouth itching occurs and is uncomfortable, then spit out the dose and do not swallow.
- 6. If local mouth itching persists beyond 5 minutes after dosing, take an oral antihistamine. If local mouth itching persists beyond 30 minutes after taking the antihistamine, call our office.
- 7. If any suspected systemic allergy symptoms occur, follow the instructions outlined below.
- 8. When dosing is completed, check the appropriate boxes on the Treatment Record
- 9. Any adverse events associated with the dosing should be recorded in the "Remarks" section (and continued on the back of the sheet if necessary).
- 10. If you are unsure of any dosing, please call our office for advice.

PRECAUTIONS:

- 1. Always be certain that your oral antihistamines and your Epinephrine Auto-injector are available at the time of dosing.
- 2. Prescription vials should be kept refrigerated for optimum maintenance of potency. However, studies have shown that the extracts are stable at room temperatures for many days. Avoid extreme heat or freezing of the extract vials.
- 3. Always check the vial labels before dosing, to be certain that you have the correct vial.
- 4. Do not take drops if you are running fever > 99.5, if you are wheezing or have a Peak Flow reading < 80% of your personal best, or if you have any open sores or wounds in the mouth.
- 5. Do not dose on days of dental procedures.
- 6. Dose adjustments based on missed days or adverse reactions are outlined below.
- 7. Do not take allergy drops if you are also taking a prescription beta blocker medication.
- 8. For women of child-bearing age, notify our office if you become pregnant.

■ DOSAGE ADJUSTMENTS BASED ON INTERVAL BETWEEN TREATMENTS / LOCAL ADVERSE REACTIONS:

MISSED DA	<u>AYS</u> : ⇒⇒	DOSAGE ADJUSTMENT:	LOCAL RI	EACTION: ⇒⇒	RESPONSE:
			a.	No reaction ⇒	 a.
a.	1-7 days ⇒	a. Continue advancement <u>or</u> repeat			continue maintenance dosing.
		the maintenance dose.	b.	Itching of mouth	 Take an oral antihistamine as needed.
			C.	Swelling of lips / tongue ⇒	 c. Take an oral antihistamine as needed; to last tolerated dose, repeat x 2; then
b.	8-14 days ⇒	b. Start over with the vial(s) most			continue advancement.
		recently used: Week 1 – 1 drop daily Week 2 – 2 drops daily	d.	Nausea or cramping ⇒	d. Take an oral antihistamine. If symptoms persist, use EPI and call 911. Call our office before taking further doses.
		Week 3 – 3 drops daily, then resume scheduled dosing.	e.	Hives ⇒	e. Take an oral antihistamine. If symptoms persist, use EPI and call 911. Call our office before taking further doses.
c.	> 14-days ⇒	c. Call our office for instructions	f.	Throat tightness / wheeze ⇒	f. Take oral antihistamine, use EPI and call 911. Call our office and arrange a follow-up visit before further dosing.

■ TREATMENT OF SYSTEMIC ADVERSE REACTIONS TO ALLERGEN IMMUNOTHERAPY:

There is always the possibility of a systemic allergic reaction (anaphylaxis) to one of the doses, even though the same dose may have been previously well tolerated. Anaphylactic symptoms may include progressive itching (nose, throat, eyes, skin, palms of hands, soles of feet, groin, etc.), sneezing, coughing, nasal congestion / drainage, throat tightness, wheezing, asthma, nausea, vomiting, abdominal cramping, diarrhea, generalized hives. Rarely, hypotension and fainting may occur. At the first signs of any systemic reaction, give at once 0.15 – 0.30 cc of 1:1000 aqueous epinephrine intramuscularly. In other words, use your Epipen Auto-injector according to the instructions on the device immediately. <u>CALL 911</u>. Depending on the nature and severity of the reaction, this dose of epinephrine may be repeated at 5-10 minute intervals. A short-acting antihistamine should also be given by

PLEASE NOTE: IF ANY SYSTEMIC REACTION OCCURS, YOU MUST RETURN TO OUR OFFICE FOR FURTHER INSTRUCTIONS PRIOR TO TAKING ANY MORE SUBLINGUAL IMMUNOTHERAPY.

Questions? Please call us at 919-787-1374.

IMMUNOTHERAPY: "Escalation (Build-Up) Phase Protocol"

Congratulations on beginning your new sublingual immunotherapy prescription! The doses during the initial 12 weeks are advancement doses. The purpose of this "Escalation (Build-Up) Phase" is to stimulate your immune system to develop immunity or tolerance to the allergens which are causing your symptoms. The escalation phase involves beginning at a low concentration and advancing until your reach a target maintenance dose of three (3) drops once daily in the highest concentration ("Maintenance"). The dosing regimen for the Escalation Phase is outlined below:

FIRST	SECOND	THIRD	FOURTH		
1 11/01	SECOND	שווווו	TOURTH		
ESCALATION VIAL(S) #1 FSCALA	ΓΙΟΝ VIAL(S), #2	ESCALATION VIAL(S), #3	ESCALATION VIAL(S), #4	
LOCALATION VIAL	j, π i LOUALA	11014 11712(0), #2	LOUALATION VIAL(U), #3	LOCALATION VIAL(O), #4	
2007127111011 11712(0), " · · · · · · · · · · · · · · · · · ·	11011 11112(0), 112	2007127111011 11112(0), 110	2007(27110)(17)(2(0)), 111	

	VIAL(S) #1 Dose from each vial:		VIAL(S) #2 Dose from each vial:		VIAL(S) #3 Dose from each vial:			VIAL(S	,
Week	Dose		Week	Dose	Week	Dose		Week	Dose
1	1 drop		4	1 drop	7	1 drop		10	1 drop
2	2 drops		5	2 drops	8	2 drops		11	2 drops
3	3 drops		6	3 drops	9	3 drops		12	3 drops

As you begin this escalation phase, there are several factors to keep in mind concerning your treatment:

- (1) During this phase, *advancement* is the operative word. You must remain consistent and regular with your dosing in order to be able to reach maintenance levels in a reasonable amount of time (12 weeks).
- (2) Keep in mind that your extract vials carry a 6-month expiration as long as they are refrigerated, so consistency is important, as expired extract vials should not be used. If they are not refrigerated, they will expire in 1 month.
- (3) If you miss a dose periodically, do not worry. Adjustment recommendations are found in your instruction packet, and, of course, you may always call the office for advice at any time.
- (4) When you are nearing completion of advancement, and you are nearing depletion of the escalation vials, you should schedule a follow-up visit with your Capitol ENT physician, in order to review your progress and to discuss the "Maintenance Phase" of your immunotherapy.
- (5) ► SCHEDULE YOUR FOLLOW-UP VISIT FOR ABOUT 2 MONTHS AFTER STARTING YOUR TREATMENT.
- (6) You will find an attached prescription for an Epinephrine Auto-injector, which you may fill and should have available at the time of your dosing. This can be used for the initial treatment of any systemic reaction that might begin. If you have questions concerning this Auto-injector, please ask your Capitol ENT physician or one of the nurses. We also suggest that you always have an oral antihistamine available for use at the time of dosing, in the event of mild local reactions.
- (7) As you approach maintenance immunotherapy, you should notice fewer flares of symptoms and (hopefully) less need for medications. Please let us know if you have questions concerning any reduction in medications, as there may be specific guidelines depending upon which medication is being adjusted. You should plan on a follow-up visit with your Capitol ENT physician about every 6-12 months to review your treatment and to make any necessary adjustments in your maintenance dose. After completion of the initial advancement phase, renewal prescriptions will consist of the Maintenance vials only, and you will remain on this maintenance concentrate for the duration of treatment (2-4 years).

Best wishes for success with your immunotherapy treatment!

If you have questions or concerns at any time, please feel free to call us at 919-787-1374.

DOSAGE PROTOCO PATIENT:	LOXIKE	AIWEN	I KECOKD - 3L	.II (INI)		RESCRIPITON)	VIAL EXP	DATIO	PAGE 4
NO. / DOB:						DO NOT USE			
Please follow the dose						ate, health scree	n, peak flow	reading	(if applicable), and number stments in dosing, based or
adverse reactions or m Please record all doses fron his page. Continue drops he refill notation, then call make arrangements for renewal protocol is outlined of DO NOT USE EXPIRED VIA	issed dose n these vials until you rea our office a renewals. To n Page 6.	s, may bon		2. SCREEN: adverse reaction Ith status withing dications since ord Peak Flow	ons to the n the last the last d reading.	last dose? 24 hours? lose?	Each bottle is name and clin G = Grasses, Mites, and/or expiration dat	labeled wic ID nun W = W Cockroa	with the following information: patienther; vaccine contents (T = Treefeeds, M = Molds, D = Dust, Duach; AD = Animal Dander); allowing complete list of specific allergion request from our office.
BOX 1: "FIRST	BUILD	-UP"		(ADVANC					
DAY: DATE	Health Screen	PEAK FLOW	<u>"A" VIAL</u>	DOSE (drops)	\square	<u>"B" VIAL</u>	DOSE (drops)	\square	REMARKS
1:			FIRST BUILD-UP VIAL	1		FIRST BUILD-UP VIAL	1		
2:			FIRST BUILD-UP VIAL	1		FIRST BUILD-UP VIAL	1		
3:			FIRST BUILD-UP VIAL	1		FIRST BUILD-UP VIAL	1		
4:			FIRST BUILD-UP VIAL	1		FIRST BUILD-UP VIAL	1		
5:			FIRST BUILD-UP VIAL	1		FIRST BUILD-UP VIAL	1		
6: 			FIRST BUILD-UP VIAL	1		FIRST BUILD-UP VIAL	1		
7:			FIRST BUILD-UP VIAL	1		FIRST BUILD-UP VIAL	1		► <u>CALL OFFICE</u> AND REPORT PROGRESS
8:			FIRST BUILD-UP VIAL	2		FIRST BUILD-UP VIAL	2		
9:			FIRST BUILD-UP VIAL	2		FIRST BUILD-UP VIAL	2		
10:			FIRST BUILD-UP VIAL	2		FIRST BUILD-UP VIAL	2		
11:			First BUILD-UP VIAL	2		First BUILD-UP VIAL	2		
12:			First BUILD-UP VIAL	2		First BUILD-UP VIAL	2		
13:			First BUILD-UP VIAL	2		First BUILD-UP VIAL	2		
14:			First BUILD-UP VIAL	2		First BUILD-UP VIAL	2		
15:			First BUILD-UP VIAL	3		First BUILD-UP VIAL	3		
16:			First BUILD-UP VIAL	3		First BUILD-UP VIAL	3		
17:			First BUILD-UP VIAL	3		First BUILD-UP VIAL	3		
18:			First BUILD-UP VIAL	3		First BUILD-UP VIAL	3		
19:			First BUILD-UP VIAL	3		First BUILD-UP VIAL	3		
20:			First BUILD-UP VIAL	3		First BUILD-UP VIAL	3		
21:			First Build-UP VIAL	3		First Build VIAL	3		

(drops L 1 L 1 L 1 L 1 L 2 L 2 L 2		REMARKS ► CALL OFFICE AND REPORT PROGRESS, SCHEDULE APPT. WITH PHYSICIAN FOR CHECK UP
1 1 1 1 1 1 1 1 2 1 2 1 2 2 2 2 2 2 2 2		REPORT PROGRESS, SCHEDULE APPT. WITH PHYSICIAN FOR CHECK
1 1 1 1 1 1 1 2 1 2 1 2 1 2 2 2 2 2 2 2		REPORT PROGRESS, SCHEDULE APPT. WITH PHYSICIAN FOR CHECK
1 1 1 1 1 1 2 2 2 2 2 2 2		REPORT PROGRESS, SCHEDULE APPT. WITH PHYSICIAN FOR CHECK
1 1 1 1 1 1 1 2 1 2 1 2 1 2 2 2 2 2 2 2		REPORT PROGRESS, SCHEDULE APPT. WITH PHYSICIAN FOR CHECK
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2 2 2 2 2 2		REPORT PROGRESS, SCHEDULE APPT. WITH PHYSICIAN FOR CHECK
2 L 2 L 2		REPORT PROGRESS, SCHEDULE APPT. WITH PHYSICIAN FOR CHECK
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DAY:	DATE	Health Screen	PEAK FLOW	<u>"A" VIAL</u>	DOSE (drops)	$\overline{\mathbf{A}}$	<u>"B" VIAL</u>	DOSE (drops)	$\overline{\mathbf{A}}$	REMARKS
43:			12011	THIRD BUILD-UP VIAL	1		THIRD BUILD-UP VIAL	1		
44:				THIRD BUILD-UP VIAL	1		THIRD BUILD-UP VIAL	1		
45:				THIRD BUILD-UP VIAL	1		THIRD BUILD-UP VIAL	1		
46:				THIRD BUILD-UP VIAL	1		THIRD BUILD-UP VIAL	1		
47:				THIRD BUILD-UP VIAL	1		THIRD BUILD-UP VIAL	1		
48:				THIRD BUILD-UP VIAL	1		THIRD BUILD-UP VIAL	1		
49:				THIRD BUILD-UP VIAL	1		THIRD BUILD-UP VIAL	1		
50:				THIRD BUILD-UP VIAL	2		THIRD BUILD-UP VIAL	2		
51:				THIRD BUILD-UP VIAL	2		THIRD BUILD-UP VIAL	2		
52:				THIRD BUILD-UP VIAL	2		THIRD BUILD-UP VIAL	2		
53:				THIRD BUILD-UP VIAL	2		THIRD BUILD-UP VIAL	2		
54:				THIRD BUILD-UP VIAL	2		THIRD BUILD-UP VIAL	2		
55:				THIRD BUILD-UP VIAL	2		THIRD BUILD-UP VIAL	2		
56:				THIRD BUILD-UP VIAL	2		THIRD BUILD-UP VIAL	2		
57:				THIRD BUILD-UP VIAL	3		THIRD BUILD-UP VIAL	3		
58:				THIRD BUILD-UP VIAL	3		THIRD BUILD-UP VIAL	3		
59:				THIRD BUILD-UP VIAL	3		THIRD BUILD-UP VIAL	3		
60:				THIRD BUILD-UP VIAL	3		THIRD BUILD-UP VIAL	3		► COME TO OFFICE FOR F/U VISIT, BRING TREATMENT RECORD ONLY 3-4 MORE WEEL OF DROPS LEFT
61:				THIRD BUILD-UP VIAL	3		THIRD BUILD-UP VIAL	3		
62:				THIRD BUILD-UP VIAL	3		THIRD BUILD-UP VIAL	3		
3:				THIRD BUILD-UP VIAL	3		THIRD BUILD-UP VIAL	3		
ou nov ordered NT phy	your mainten	s of drops ance vials the next w	. If you l eek, so	ing in your vial(s have not, call our that there will be	office now	(TEL	919-787- <mark>1374)an</mark>	d arrange	a follov	cian for a check-up and v-up visit with your Cap pare your renewal vials
Dosag	E PROTOCO	L & TRF	ATMFN	r Record - SL	. IT (INIT	AI PRF	SCRIPITON)			PAGE 7
	T:	,			- (11411		,	VIAL EXP	DATIO	

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VIAL EXPIRATION DATE:

KEEP VIALS REFRIGERATED.

DO NOT USE EXPIRED VACCINE VIALS.

Dosage Protocol & Treatment Record - SLIT (INITIAL PRESCRIPITON)

PATIENT:

NO. / DOB:

NO. / DOB:		DO NOT USE EXPIRED VACCINE VIALS.
		KEEP VIALS REFRIGERATED.

BOX 4: "FOURTH BUILD-UP" VIALS (ADVANCING DOSES)

							NO DOOLO ,			
DAY	DATE	Health	PEAK	<u>"A" VIAL</u>	DOSE	$\overline{\mathbf{Q}}$	"B" VIAL	DOSE	$\overline{\mathbf{Q}}$	DEMA DIZO
DAY:	DATE	Screen	FLOW		(drops)			(drops)		REMARKS
64:				FOURTH	1		FOURTH	1		
				BUILD-UP VIAL	ı	J	BUILD-UP VIAL	ı	•	
65:				FOURTH	1		FOURTH	1		
				BUILD-UP VIAL	'		BUILD-UP VIAL			
66:				FOURTH	1		FOURTH	1		
				BUILD-UP VIAL	<u> </u>		BUILD-UP VIAL			
67:				FOURTH	1		FOURTH	1		
				BUILD-UP VIAL	•		BUILD-UP VIAL	•		
68:				FOURTH	1		FOURTH	1		
				BUILD-UP VIAL	•		BUILD-UP VIAL	•		
69:				FOURTH	1		FOURTH	1		
				BUILD-UP VIAL			BUILD-UP VIAL	•		
70:				FOURTH	1		FOURTH	1		
				BUILD-UP VIAL			BUILD-UP VIAL			
71:				FOURTH	2		FOURTH	2		
70				BUILD-UP VIAL			BUILD-UP VIAL			
72:				FOURTH	2		FOURTH	2		
70				BUILD-UP VIAL			BUILD-UP VIAL			
73:				FOURTH	2		FOURTH	2		
				BUILD-UP VIAL			BUILD-UP VIAL			
74:				FOURTH	2		FOURTH BUILD-UP VIAL	2		
75:				BUILD-UP VIAL		_	FOURTH			
75:				FOURTH BUILD-UP VIAL	2		BUILD-UP VIAL	2		
76:				FOURTH		_	FOURTH			
70.				BUILD-UP VIAL	2		BUILD-UP VIAL	2		
77:				FOURTH			FOURTH			
11.				BUILD-UP VIAL	2		BUILD-UP VIAL	2		
78:				FOURTH	3		FOURTH	3		
70.				BUILD-UP VIAL	3		BUILD-UP VIAL	3		
79:				FOURTH	3		FOURTH	3		
10.		_		BUILD-UP VIAL	J	ш	BUILD-UP VIAL	3	Ч	
80:				FOURTH	3		FOURTH	3		
00.		_		BUILD-UP VIAL	S	ч	BUILD-UP VIAL	S		
81:				FOURTH	3		FOURTH	3		
V 1.		_		BUILD-UP VIAL	J	Ч	BUILD-UP VIAL	S	_	
82:				FOURTH	3		FOURTH	3		
V=1		_		BUILD-UP VIAL	J	Ч	BUILD-UP VIAL	3	_	
83:				FOURTH	3		FOURTH	3		
		J		BUILD-UP VIAL	J	Ч	BUILD-UP VIAL	3	_	
84:				FOURTH	3		FOURTH	3		
2		J		BUILD-UP VIAL	J	_	BUILD-UP VIAL	J	_	

MAINTENANCE PROTOCOL:

Congratulations! You have now reached the standard maintenance level for your sublingual immunotherapy. At this point, you should have already seen your Capitol ENT physician for a follow up appointment, and you should have picked up your first maintenance vial, or it should have already been mailed to you. Continue to apply 3 drops once daily. Questions? Call 919-787-1374.