

INSTRUCTIONS: Complete this form each time a re-uptitration is required during the maintenance phase. The form will be entered in the “Study Drug Maintenance” event.

Section A: KEY IDENTIFYING INFORMATION

- A1. Study Identification Number _____ - _____ - _____ - _____
- A2. Study drug assigned
 STUDY DRUG A 1
 STUDY DRUG B 2
- A3. Prescription number _____
- A4. Date of form completion
 ___ ___ / ___ ___ / ___ ___ ___ ___
 M M D D Y Y Y Y
- A5. Name of person completing form

 PRINT FULL NAME INITIALS

Section B: SAFETY ASSESSMENT

- B1. Date of check-up call
 ___ ___ / ___ ___ / ___ ___ ___ ___
 M M D D Y Y Y Y
- B2. Is subject reporting any drug intolerances? YES 1 NO 2 (B3)

Record all intolerances reported by subject/parent. Be certain to provide answers to ALL questions listed (a-e).

		YES	NO
a.	Dizziness interfering with activities of daily living	1	2
b.	Fatigue interfering with activities of daily living	1	2
c.	Syncope	1	2
d.	Shortness of breath interfering with activities or new shortness of breath	1	2
e.	Other symptoms interfering with activities of daily living i. Specify: _____	1	2 (B3)

For subjects < 18 months of age, obtain blood pressure measures before administration of new study drug dose for each cycle. BP will be taken at study center or locally. If BP taken locally, documentation must be obtained.

- B3. Is the subject < 18 months of age? YES 1 NO 2 (C0)
 - a. Systolic blood pressure
(BEFORE administration of new dose) _____ mmHg
 - b. Diastolic blood pressure
(BEFORE administration of new dose) _____ mmHg

c. Is systolic BP < 2nd percentile for age? YES1* NO.....2
 *If YES, subject must come to study center before continuing uptitration.

Section C: HEART RATE ASSESSMENT

C0. Was an ECG done? YES.....1 (C1) NO.....2

a. Specify reason ECG was not done _____
 _____ (D1)

C1. Date of ECG _____ / _____ / _____
 M M / D D / Y Y Y Y

C2. 24 hour average heart rate (from current 24-hr ECG) _____ BPM

a. 24 hour average heart rate above threshold for age? YES.....1 NO.....2*
 • ≥ 60 BPM if < 12 months of age
 • ≥ 55 BPM if 12 – 24 months of age
 • ≥ 50 BPM if > 24 months of age
 *If NO, 24-hr ECG must be scanned

Answer the next questions only for subject randomized to study drug A (Atenolol). If subject is randomized to study drug B (Losartan), skip to question D1.

Target average heart rate, represents minimum 20% decrease from baseline _____ BPM (not data entered)

b. Is the current average heart rate below the target average heart rate? YES.....1* NO.....2
 *If YES, stop uptitration. Current dose is maintenance dose.

Section D: ASSESSMENT OUTCOME

D1. What is the outcome of the above assessments? CONTINUE RE-UPTITRATION1 (E1)
 END RE-UPTITRATION2 (F1)

Section E: STUDY DRUG RE-UPTITRATION

E1. Date of uptitration (Date Rx was changed) _____ / _____ / _____
 M M / D D / Y Y Y Y

Previous dose administered (report DAILY dose from previous cycle) _____ mg (See last form A120)

Subject weight _____ kg (See last form A120)

- E2. Dose prescribed _____ . _____ mg/kg
(Enter '-5' if subject at MAX dose of study drug)
- E3. Study drug administration DAILY 1
TWICE A DAY (b.i.d) 2
- E4. Dose to administer per day _____ . _____ mg/day **(Z1)**

Please fill out another Form A123 for continuing re-uptitration during study drug maintenance.

Section F: END RE-UPTITRATION

- F1. Date subject reached the maintenance dose, highest tolerated dose, or maximum allowable dose of study drug
- _____ / _____ / _____
M M D D Y Y Y Y

Section Z: TIME TO COMPLETE FORM

- Z1. How long did it take to complete this form? _____ minutes

END OF FORM