



Affix Patient I.D. Here

1 Date symptoms noted or evaluated: DATE 08 / /
mo dy yr

REASON FOR COMPLETION

2 1 Baseline (6 days post MI to present).

REASON 08 2 Open label titration.

3 Scheduled followup (specify):

- | | | | |
|-----------|---|---|----------------------------------|
| | <input type="checkbox"/> 1 4 mo | <input type="checkbox"/> 2 8 mo | <input type="checkbox"/> 3 1 yr |
| | <input type="checkbox"/> 4 1 yr + 4 mo | <input type="checkbox"/> 5 1 yr + 8 mo | <input type="checkbox"/> 6 2 yr |
| FOLLOW 08 | <input type="checkbox"/> 7 2 yr + 4 mo | <input type="checkbox"/> 8 2 yr + 8 mo | <input type="checkbox"/> 9 3 yr |
| | <input type="checkbox"/> 10 3 yr + 4 mo | <input type="checkbox"/> 11 3 yr + 8 mo | <input type="checkbox"/> 12 4 yr |
| | <input type="checkbox"/> 13 4 yr + 4 mo | <input type="checkbox"/> 14 4 yr + 8 mo | <input type="checkbox"/> 15 5 yr |

4 Unscheduled event.

5 Blinded retitration.

STUDY DRUG AT TIME OF EVALUATION

3 THERAP 08 1 No drug (before open label titration)

2 CAST Therapy

DRUG 08

1 CAST-ENC

2 CAST-FLEC

3 CAST-MOR

1 Dose 1

2 Dose 2

3 Other: mg/day

3 Washout

DOSE 08

4 Individualized Therapy

IT 08

1 No antiarrhythmic therapy

2 Non-CAST antiarrhythmic therapy

specify:

ADVERSE CLINICAL SYMPTOMS

SYMPTOMS

4 Are there any adverse clinical symptoms? ₁ yes ₂ no
If YES, complete the sections below.

For each body system listed, indicate the severity of the adverse symptom. If Severe is checked, write in the specific adverse symptom below and check the box under Drug Related. See back of this form for list of adverse symptoms and definitions of Mild and Severe.

		None Mild Severe			Drug Related			not deter- mined																															
		<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	yes	poss- ible	no																																
5	Dermatological DERMØS	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉	DRDERMØS																														
6	Ocular OCULARØS	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉	DROCULØS																														
7	Gastrointestinal GIØS	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉	DRGIØS																														
8	Genitourinary GUØS MUSCLEØS	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉	DRGUØS																														
9	Musculoskeletal	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉	DRMUSCØS																														
10	Neurological NEURØS	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉	DRNEURØS																														
11	Pulmonary PULMONØS	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉	DRPULMØS																														
12	Cardiovascular CARDVØS	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉	DRCARDØS																														
13	Other OTHSYMØS	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₉	DROTHØS																														
14	Specify severe symptoms:	<table border="1"> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </table>																																					

If new or worsened CHF, complete New or Worsened CHF form, CAST 19

ADVERSE ECG EFFECTS OR ARRHYTHMIA CHANGES

15 Subsequent to baseline, have there been any adverse changes in the patient's arrhythmia or ECG intervals since the last evaluation?
(DO NOT COMPLETE AT BASELINE).
₁ yes ₂ no ECGSYMØS

If YES,
Check all that apply:

16 ₁ Proarrhythmia per stated criteria
(see back of form) for VPD's.
PROARRØS VPD's/hr:

Drug Related
not
deter-
mined
yes no
₁ ₂ ₉
VPDSØS DRVPDSØS

If washout, VPD's/hr after: WCVPSØS



Drug Related

not determined

yes no not determined
[]₁ []₂ []₉
DRRUNS08

17 []₁ Proarrhythmia per stated criteria (see back of form) by VPD runs

PRORUN08

VPD runs at a rate \geq 120 bpm: [] [] [] [] []

If washout, runs after: [] [] [] [] []

18 []₁ Excessive VPD's (\geq 1500 VPD's/hr independent of pretreatment frequency)

EXCVPD08

VPD's/hr: [] [] [] [] [] EXVPDS08

If washout, VPD's/hr after: [] [] [] [] []

19 []₁ Symptomatic (hemodynamically important) unsustained VT or VT \geq 15 consecutive complexes at a rate of \geq 120 bpm (disqualifying VT). Complete VT form, CAST 21.

VT08

[]₁ []₂ []₉
DRVT08

20 []₁ QTc prolongation \geq 1.4 times baseline or \geq 0.6 secs. QTc08

QTLONG08

QTc (QT/RR): 0. [] [] [] [] [] secs. WOQTc08
If washout, QTc after: 0. [] [] [] [] [] secs.

[]₁ []₂ []₉
DRQTc08

21 []₁ Heart rate $<$ 30 bpm lasting at least 1 minute.

HRSLW08

Rate: [] [] [] [] [] bpm HR08

If washout, rate after: [] [] [] [] [] bpm WOHR08

[]₁ []₂ []₉
DRHR08

22 []₁ Any single pause \geq 3.5 second.

PAUSE08

Pause: [] [] [] [] [] secs. LPAUSE08

If washout, pause after: [] [] [] [] [] s cs. WOPAUSE08

[]₁ []₂ []₉
DRPAUSE08

23 []₁ Mobitz II 2°, advanced, or 3° AV block.

MPBITZ08

[]₁ []₂ []₉
DRMOB08

24 []₁ QRS \geq 2 times baseline or QRS \geq 0.20 secs.

QRSLNG08

QRS: 0. [] [] [] [] [] secs. WOQRS08
If washout, QRS after: 0. [] [] [] [] [] secs.

[]₁ []₂ []₉
DRQRS08

25 Was a permanent pacemaker implanted?

PACE08 []₁ yes []₂ no

26 If more than one of any of the following are checked:

- 1) a SEVERE symptom on lines 5-13 and/or
- 2) any adverse ECG effect or arrhythmia change on lines 16-24, enter the LINE NUMBER for the most significant symptom/effect:

[] [] [] [] [] MSTIMP08

Name of person filling out form

[] [] [] [] [] Code Number