

**Optimizing heart failure care
from hospital discharge to patient follow-up**

Multi-center patient support program

N IC4 -16257 -025 – RUS

Check list for follow up HF pts with systolic dysfunction

City _____

Name of the patient care institution _____

Doctor's name _____

Doctor's phone number __ (____) _____

Patient's name _____

Patient's gender _____

Patient's age _____

Check list for follow up HF pts with systolic dysfunction

| Parametrs | Hospital | Outpatient stage | | | | | | | | | | | | | | | |
|---|--------------------------------|---------------------------------|------------------|------------------|------------------|--------------------------------|------------------|------------------|--------------------------------|------------------|------------------|--------------------------------|------------------|------------------|--------------------------------|------------------|------------------|
| | (before discharge) | V 1 7 - 14 D after discharge | | | | V2 1 M (+14D) | | | V 3 3 M(+14D) | | | V 4 6 M (+14D) | | | V 5 12 M (+14D) | | |
| | Date_____ | Date_____ | | | | Date_____ | | | Date_____ | | | Date_____ | | | Date_____ | | |
| Weight, kg | _____ | _____ | | | | _____ | | | _____ | | | _____ | | | _____ | | |
| Height, sm | _____ | _____ | | | | _____ | | | _____ | | | _____ | | | _____ | | |
| HR (by ECG), bpm | _____ | _____ | | | | _____ | | | _____ | | | _____ | | | _____ | | |
| SBP/DBP mmHg | _____ | _____ | | | | _____ | | | _____ | | | _____ | | | _____ | | |
| Sign of congestion: | | _____ | | | | _____ | | | _____ | | | _____ | | | _____ | | |
| crepitation/crackles | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no |
| ↑Hepar | yes | yes | yes | yes | yes | yes | yes | yes | yes | yes | yes | yes | yes | yes | yes | yes | yes |
| peripheral edema | no | no | no | no | no | no | no | no | no | no | no | no | no | no | no | no | no |
| NYHA class | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV | II III IV |
| LVEF, % | _____ | _____ | | | | _____ | | | _____ | | | _____ | | | _____ | | |
| Rhythm | Sinus Other, please specify | Sinus Other, please specify | | | | Sinus Other, please specify | | | Sinus Other, please specify | | | Sinus Other, please specify | | | Sinus Other, please specify | | |
| Creatinine, mkmol/l | _____ | _____ | | | | _____ | | | _____ | | | _____ | | | _____ | | |
| K+, mmol/l | _____ | _____ | | | | _____ | | | _____ | | | _____ | | | _____ | | |
| EchoCG** | (date)_____ | (date)_____ | | | | (date)_____ | | | (date)_____ | | | (date)_____ | | | (date)_____ | | |
| QoL (points)*** | (date)_____ | (date)_____ | | | | (date)_____ | | | (date)_____ | | | (date)_____ | | | (date)_____ | | |
| Compliance by the patient self-testing conditions? (outline) | | | | | | | | | | | | | | | | | |
| Weight check (2 times/week) | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no |
| Diet adherence | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no |
| Cheking HR and BP | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no | yes no |
| Pts education | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 | 1 2 3 4 |
| Recurrent hospitalization or withdrawal(W) | | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W | Hospit. W |
| | | cause_____ | | | | cause_____ | | | cause_____ | | | cause_____ | | | cause_____ | | |
| | | _____ | | | | _____ | | | _____ | | | _____ | | | _____ | | |
| | | date | | | | date | | | date | | | date | | | date | | |
| | | _____ | | | | _____ | | | _____ | | | _____ | | | _____ | | |

| | | | | | | | | | | | | | | | |
|--|-------------------------|------------------------------|-------------------------|-------------------------|------------------------------|-------------------------|------------------|------------------------------|-------------|------------------|------------------------------|-------------|------------------|------------------------------|-------------|
| Other clinical events since the last visit | | Diagnosis Date | Diagnosis Date | Diagnosis Date | Diagnosis Date | Diagnosis Date | | | | | | | | | |
| Guidelines based prognosis-modifying pharmacotherapies* | | | | | | | | | | | | | | | |
| ACEi/sartans | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | | | | | | | | | |
| BB | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | | | | | | | | | |
| MRA | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | | | | | | | | | |
| Ivabradine | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | Y N contra-indicated | | | | | | | | | |
| Pts' adherence | hi gh | m o d er at e | l o w | h i g h | m o d er at e | l o w | h i g h | m o d er at e | l o w | h i g h | m o d er at e | l o w | h i g h | m o d er at e | l o w |

*- ACEi – if LVEF ≤40% (cough or intolerance – sartans)

BB- if LVEF ≤40%

MRA – if LVEF ≤35%, K+<5.0 mmol/l, creatinine<200mkmol/l

Ivabradine – a) if sinus rhythm and Pts treated with BB but HR>70 bpm; b) if BB contra-indicated

** EchoCG – at least 2 times per observation (timeline – Drs' decision)

***QoL assessment (points) - by Scale of the Russian Society of Heart Failure

Please fill in the Adverse Event Form **Pharmacovigilance form** (see attachment Annex I) **and fax it (495) 937-47-66** to Servier if the followings occurred:

- serious adverse drug reactions related to Servier drug intake
- non-serious adverse drug reactions related to Servier drug intake
- adverse events in relation to Servier drug withdrawal

Reports of special situations (see the Protokol)

In case of serious adverse reaction or serious adverse event in relation to Servier drug withdrawal, the Adverse Event Form should be filled in and sent by fax within 24 hours. In other cases – within 2 days.

ANNEX 1

PHARMACOVIGILANCE FORM

The report about an adverse reaction/adverse event related to Servier drug withdrawal in Optimize heart failure care study

Please send this form immediately by fax 8(495) 937-47-66 (for N.Korneeva)

Initial report Follow up report

Date of birth:

Gender:

|_|_|·|_|_|·|_|_|_|_| year

M F

Height: |_|_|_|cm

Weight: |_|_|_|kg

Patient's initials |_|_|_|

Description of the adverse reaction:

Onset date

Date of recovery

|_|_|·|_|_|·

|_|_|·|_|_|·

|_|_|_|_| year

|_|_|_|_| year

General disease(s)/concomitant disease(s) (report the date of the diagnosis establishment)

Course of the adverse event (report the appropriate information, for example, the results of the analyses, of the histological examination and of other examinations, the data from the discharge letter e t.c.)

Seriousness criteria:

- No Yes (specify, choose from the list below)
- fatal outcome
- life-threatening
- hospitalization or prolongation of hospitalization
- permanent disability
- birth defect
- medically-important event

Relationship with the Servier drug

No Yes

If yes, please, specify the drug

recovered _____
the date of recovery

- the patient didn't recover
- outcome is unknown
- permanent functional/structural disorder
- fatal outcome

Therapy prescribed for treatment of this adverse reaction

Outcome:

The list of taken drugs

Daily dose/route

Dates of intake:

Indication

from _____ to _____

1

2

3

4

Physician's surname, name, patronymic:

Profession:

Work address:

Phone number: 8(____)_____

Date:

Signature:

