**CASE REPORT FORM**



National multicentral Observational Programm

Evaluation of the efficacy and tolerability of a fixed dose combination of amlodipine and indapamide (ARIFAM) in patients older than 55 years

Protocol № IC4-05520-047-RUS

National coordinator:

Professor Yu.M. Lopatin, MD, Professor

Surname, name, patronymic of the doctor:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Specialty profession: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Clinic\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Doctor’s phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Surname, name, patronymic of the patient:\_ |\_\_ |\_\_ |\_\_|

*Document:* PATIENT INFORMATION AND INFORMED CONSENT FORM FOR PARTICIPATION IN THE PROGRAM, as attached to the Protocol NIC4-06795-051-RUS

*Name of the program:* MODUS *vivendi*

*Study drug:* PREDUCTAL OD

*Indication for use:* Long treatment of IHD: prevention of angina attacks as a part of mono- or combined therapy

 *Phase of the study:* Postmarketing observational program

*Protocol code:* IC4-06795-051-RUS

*Country code:* RUS

*Sponsor's Representative:* Servier JSC

*Document date:* Final version dated …

*CONFIDENTIAL*

**PATIENT INFORMATION AND INFORMED CONSENT FORM**

You are invited to participate in the observational study. It is important that before deciding, you understand why this observational program is being conducted and what it will include. Please spend enough time to read carefully the information below and discuss it, if necessary, with your doctor. If you do not understand something or you want to get additional information, ask questions to the doctor responsible for the observational program.

Please take enough time when making your decision on whether to participate in the study or not. Please note that your participation in the study will not affect your current treatment.

If you decide to participate in the study, you will be asked to complete, sign and date this Patient Information and Informed Consent Form for participation in the study. You will be also asked to keep this form, as it provides useful information about the details of the study and the contact phone of the doctor.

This program is organized and funded (i.e. sponsored) by Servier JSC.

**Aim of the study**

To assess the efficacy, tolerability, and the effects on the quality of life for 3-month treatment with Preductal OD 80 mg added to bisoprolol in patients with ischemic heart disease and angina symptoms in daily practice.

**Information about the drug**

The drug is registered for use by the Ministry of Health of the Russian Federation; number of marketing authorization: № ЛП-003410 13.01.2016

It is important that you understand that your treatment will not be changed in any way due to your participation in this observational study. Your doctor will prescribe to you those medications and investigations that are usually prescribed for your disease.

**Participation in the study**

The present study is planned to include a total of 2000 patients suffering from ischemic heart desease (250 doctors will enroll 8 patients each). You were invited to participate in this study because you are diagnosed ischemic heart disease you have angina attack on current treatment, and your doctor considers it necessary to add PREDUCTAL OD to the treatment of this disease.

You must decide on your own whether you will participate in this observational study or not. If you agree to participate in the study, you reserve the right to refuse to participate in the study at any time. In this case, the doctor responsible for the monitoring program may ask you about the reasons for your refusal. Your decision to stop participating in the study will not affect the quality of your medical care.

**Procedures in the study:**

During this observational study, the data on your treatment will be recorded for 12 weeks. If you stop PREDUCTAL OD treatment before the end of this study, the doctor can still continue to record PREDUCTAL OD safety data until he/she considers it necessary. In either case, the doctor will continue to observe you in accordance with normal medical practice.

During the study, the doctor will collect certain information about you. It will include personal data (for example, your initials, gender, age,) and your health status (for example, the history of your disease, current treatment, and concomitant diseases). In order to contact you, the doctor will ask you to tell him/her your contact details.

**Responsibility and duties of a patient:**

Your daily activity will not be changed and will not be limited in any way due to participation in this observational study. You will continue to take those medications that have been prescribed by your doctor, to visit a doctor and to undergo an examination as necessary in the routine treatment of your disease.

Some side effects of the medications that you are taking now have already been studied and described in the instructions for use. However, the occurrence of side effects that are unknown to date cannot be excluded. Therefore, you will be asked to inform your doctor about all complains and undesirable symptoms occurring during your participation in this observational study.

**Potential benefits and risks associated with participation in the study:**

Since your participation in this observational study will not affect your treatment and examination, there is no additional benefit for you, as well as the risk or any inconvenience directly associated with participation in this study.

However, if you agree to participate in the study, you will contribute to obtaining additional information about the treatment of patients with IHD and about PREDUCTAL OD drug in the treatment of this disease.

**Provision of information during the observational study:**

During the observational program, you will be informed of any new information about your disease and treatment that may affect your decision to continue participation in the program. If you decide to stop participating in this observational program, your doctor responsible for the observational program will ensure the continuation of your treatment. If you agree to continue participating in the program, you will be asked to sign an updated Patient Information and Informed Consent Form for participation in the program.

**Confidentiality and anonymity of data:**

If you agree to participate in the observational program, all your personal data obtained during this observational program will be kept confidential. They will be used only for the purpose of assessing the follow-up and can be submitted to public health authorities in an anonymous form.

In order to verify the authenticity of the data, representatives of Servier JSC and persons working on behalf of Servier JSC, as well as representatives of public health authorities and the Ethics Committee, will be able to access your medical records or other personal information received during the program. In this case, the confidentiality of data specified in the medical records will be maintained.

Any information about you that will be passed outside the medical facility where the program is conducted will be anonymous. Any transmission of such data will occur in accordance with the rules for the protection of personal data when processing and transmitting them.

In case of a premature termination of the study, all information about you that was collected before termination of your participation in the program will be used.

**Results of the program:**

The data and results of this observational program can be published in medical journals or used in scientific reports, but your name will not be mentioned under any circumstances.

**Contacts for answers to questions:**

If during this observational program you have any questions about the nature of the program or medicines used during the observation, please contact your doctor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

by phone:

Thank you for reading this information.

**INFORMED CONSENT OF THE PATIENT**

Hereby, I (surname, first name, and patronymic name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

confirm my consent to participate in the

OPEN MULTICENTER OBSERVATIONAL PROGRAM "ARBALET".

I got an explanation about the purpose of program and action of the drug used.

I am informed that within 3 months I will need to visit the clinic \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at least 3 times, to see the doctor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and to perform the necessary examinations.

I understand that at any time I can stop participation in the program, and this will not affect my further treatment.

I am informed of a need to comply with the prescribed diet and exercise regimen, as well as the regimen of taking the drug.

The doctor , who discussed with me the question of my participation in this observational study, gave me an exhaustive explanation of the nature, purposes and duration of the study. I had the opportunity to ask him/her questions about all aspects of this observational study, and I was told the name of the person to whom I can apply for any questions arising during the study.

After due consideration, I agree to cooperate with the doctor responsible for the observational program and, if necessary, with all persons authorized by him/her. I will immediately inform them of any changes in my state of health.

Signature of a patient \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_ | \_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Doctor (surname, first name, and patronymic name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of a doctor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_ | \_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_

***To be provided to the patient***

**INFORMED CONSENT OF THE PATIENT**

Hereby, I (surname, first name and patronymic name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

confirm my consent to participate in the

OPEN MULTICENTER OBSERVATIONAL PROGRAM "ARBALET".

I got an explanation about the purpose of program and action of the drug used.

I am informed that within 3 months I will need to visit the clinic \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at least 3 times, to see the doctor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and to perform the necessary examinations.

I understand that at any time I can stop participation in the program, and this will not affect my further treatment.

I am informed of a need to comply with the prescribed diet and exercise regimen, as well as the regimen of taking the drug.

The doctor , who discussed with me the question of my participation in this observational study, gave me an exhaustive explanation of the nature, purposes and duration of the study. I had the opportunity to ask him/her questions about all aspects of this observational study, and I was told the name of the person to whom I can apply for any questions arising during the study.

After due consideration, I agree to cooperate with the doctor responsible for the observational program and, if necessary, with all persons authorized by him/her. I will immediately inform them of any changes in my state of health.

Signature of the patient \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_ | \_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Doctor (surname, first name and patronymic name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the doctor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_ | \_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_

***To be kept by the doctor***

**Visit 1 (inclusion)** Date: \_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_

**Demographic data**

* Gender: M F Age: \_\_\_\_\_\_ years

**Vital signs**

* Weight \_\_\_\_ kg
* Waist circumference \_\_\_cm
* Height \_\_\_\_\_ cm
* BP in the sitting position \_\_\_\_/\_\_\_\_mm Hg
* HR \_\_\_\_ bpm

**Medical history**

|  |
| --- |
| Year of CAD diagnosis \_\_\_\_\_\_\_\_\_ |
| Year of stable angina diagnosis \_\_\_\_\_\_\_\_\_\_ |
| Number of hospitalizations due to CAD destabilization in the last 6 months \_\_\_\_Number of calls for emergency medical services in the last 6 months \_\_\_\_This patient is examined by you: for the first time repeatedly  |
|  | Yes | No |
| Post-myocardial infarction Date of the last infarction \_\_/\_\_/\_\_\_ |  |  |
| Coronary interventions (PCI, CABG) Date of intervention \_\_/\_\_/\_\_\_ |  |  |
| Arterial hypertension |  |  |
| History of stroke and/or transient ischemic attack (TIA) |  |  |
| Heart failure |  |  |
| Asthma/COPD |  |  |
| Chronic renal disease |  |  |
| Chronic liver disease |  |  |

**Risk factors and lifestyle**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Type 2 diabetes mellitus |  |  |
| Does the patient make regular physical exercises (at least 15 minutes 3 times a week) |  |  |
| Arterial hypertension |  |  |
| Smoking |  |  |
| Dyslipidemia |  |  |
| Overweight  |  |  |
| Family history of premature CAD  |  |  |

**Present symptoms**

|  |  |  |
| --- | --- | --- |
|  | Yes  | No |
| Symptoms of angina or its equivalents |  |  |
| If Yes: The average number of angina attacks: |\_\_|\_\_| per weekThe average use of nitroglycerin per week: |\_\_|\_\_| tablets or puffs Class of angina according to the Canadian Cardiovascular Society (CCS) classification: Class I Class II Class III Class IVHow many flights of stairs the patient can climb before the occurrence of chest pain (or equivalents of angina)? \_\_\_\_\_\_\_ |
| Symptoms of CHF (shortness of breath, fatigue, swelling)  |  |  |
| If Yes: The NYHA class of CHF: Class I Class II Class III Class IV  |

**Inclusion criteria:**

- Confirmed diagnosis of CAD, class II or III stable angina.

- Treatment with bisoprolol

- Signed informed consent of a patient

- No contraindications to the prescription of PREDUCTAL OD as indicated in the instruction for use of medicinal product for medical purposes.

**Non-inclusion criteria:**

* Age below 18 years
* Class IV stable angina
* Unstable angina
* Myocardial infarction within 3 months prior to the inclusion in the program
* Cerebrovascular accident [CVA] (stroke of various cause; TIA) within 3 months prior to the inclusion in the program
* Uncontrolled arterial hypertension (BP above 180 and 100 mm Hg), despite the current antihypertensive treatment.
* Pregnancy, breastfeeding.
* Inability to understand the nature of the program and follow the recommendations.
* Presence of contraindications or known intolerance to trimetazidine.

I confirm that the patient fully meets the inclusion criteria in the program and does not comply any of the non-inclusion criteria.

Signature of the doctor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_

**Please indicate what treatment the patient received before inclusion in the program:**

|  |  |  |
| --- | --- | --- |
| Name of drug  | Trade name | Daily dose |
| Beta-blockers **(bisoprolol)**  |  |  |
| Trimetazidines (Preductal® MR 35 mg or generics)  |  |  |
| Long-acting nitrates  |  |  |
| Short-acting nitrates  |  |  |
| Calcium channel blockers  |  |  |
| Ivabradine  |  |  |
| ACE inhibitors |  |  |
| Sartans |  |  |
| Diuretics  |  |  |
| Antiplatelets |  |  |
| Lipid-lowering agents |  |  |
| Other drugs, including metabolic ones |  |  |
|  |  |  |
|  |  |  |
| Drugs for the treatment of concomitant pathology |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Treatment after inclusion in the program**

|  |  |  |
| --- | --- | --- |
| Name of drug  | Trade name | Daily dose |
| Beta-blockers **(bisoprolol)** |  |  |
| **Preductal once daily**  |  |  |
| Long-acting nitrates  |  |  |
| Short-acting nitrates  |  |  |
| Calcium channel blockers  |  |  |
| Ivabradine  |  |  |
| ACE inhibitors |  |  |
| Sartans |  |  |
| Diuretics  |  |  |
| Antiplatelets |  |  |
| Lipid-lowering agents |  |  |
| Other drugs, including metabolic ones |  |  |
|  |  |  |
|  |  |  |
| Drugs for the treatment of concomitant pathology |  |  |
|  |  |  |
|  |  |  |

**Assessment of treatment adherence**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Did you forget to take your medicine this morning? |  |  |
| Since the previous consultation, have you used all the reserve of your medicine? |  |  |
| Have you ever taken your medicine later than you usually intake it? |  |  |
| Has it ever happened that you did not take your medicine, because in some days you forgot about it? |  |  |
| Has it ever happened that you did not take your medicine, because on some days you felt that the medicine does more harm than good? |  |  |
| Do you think that you take too many tablets? |  |  |
| **SUM of Yes:** |  |  |
| **0 Yes** – good adherence; **1-2 Yes** – average adherence; **3 or more Yes** – non-adherence |

**Quality of life assessment**

Please ask the patient to fill in a short questionnaire and a visual analogue scale (VAS) for assessing well-being in ***Appendix 1 (Visit 1)***.

**PLEASE GIVE THE SELF-MONITORING DIARY TO THE PATIENT**

**Visit 2 (approximately 1 month later)** Date: \_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_

**Vital signs**

* BP in the sitting position \_\_\_\_/\_\_\_\_mm Hg
* HR \_\_\_\_ bpm

**Assessment of the treatment efficacy**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Symptoms of angina or its equivalents |  |  |
| If Yes: The average number of angina attacks: |\_\_|\_\_| per weekThe average use of nitroglycerin per week: |\_\_|\_\_| tablets or puffs Class of angina according to the Canadian Cardiovascular Society (CCS) classification: Class I Class II Class III Class IVHow many flights of stairs the patient can climb before the occurrence of chest pain (or equivalents of angina)? \_\_\_\_\_\_\_ |
| Symptoms of CHF (shortness of breath, fatigue, swelling)  |  |  |
| If Yes: The NYHA class of CHF: Class I Class II Class III Class IV  |

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| **It is recommended to continue current therapy** |  |  |

**If not, please indicate the corrected therapy in the table**

|  |  |  |
| --- | --- | --- |
| Name of drug  | Trade name | Daily dose |
| Beta-blockers **(bisoprolol)** |  |  |
| Preductal OD 80 mg |  |  |
| Long-acting nitrates  |  |  |
| Short-acting nitrates  |  |  |
| Calcium channel blockers  |  |  |
| Ivabradine  |  |  |
| ACE inhibitors |  |  |
| Sartans |  |  |
| Diuretics  |  |  |
| Antiplatelets |  |  |
| Lipid-lowering agents |  |  |
| Other drugs, including metabolic ones |  |  |
|  |  |  |
|  |  |  |
| Drugs for the treatment of concomitant pathology |  |  |
|  |  |  |
|  |  |  |

**Assessment of treatment adherence**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Did you forget to take your medicine this morning? |  |  |
| Since the previous consultation, have you used all the reserve of your medicine? |  |  |
| Have you ever taken your medicine later than you usually intake it? |  |  |
| Has it ever happened that you did not take your medicine, because in some days you forgot about it? |  |  |
| Has it ever happened that you did not take your medicine, because on some days you felt that the medicine does more harm than good? |  |  |
| Do you think that you take too many tablets? |  |  |
| **SUM of Yes:** |  |  |
| **0 Yes** – good adherence; **1-2 Yes** – average adherence; **3 or more Yes** – non-adherence  |

**Quality of life assessment**

Please ask the patient to fill in a short questionnaire and a visual analogue scale (VAS) for assessing well-being in ***Appendix 1 (Visit 2)***.

**Assessment of adverse events**

In case of reporting the adverse events or special situations, please fill in the "Pharmacovigilance Form" (see ***Appendix 2***)

For serious events, the form must be completed and sent immediately. In other cases - within 2 working days.

**PLEASE CHECK THE USE OF PATIENT'S SELF-MONITORING DIARY**

**Visit 3 (approximately 3 months later)** Date: \_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_

**Vital signs**

* BP in the sitting position \_\_\_\_/\_\_\_\_mm Hg
* HR \_\_\_\_ bpm

**Assessment of the treatment efficacy**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Symptoms of angina or its equivalents |  |  |
| If Yes: The average number of angina attacks: |\_\_|\_\_| per weekThe average use of nitroglycerin per week: |\_\_|\_\_| tablets or puffs Class of angina according to the Canadian Cardiovascular Society (CCS) classification: Class I Class II Class III Class IVHow many flights of stairs the patient can climb before the occurrence of chest pain (or equivalents of angina)? \_\_\_\_\_\_\_ |
| Symptoms of CHF (shortness of breath, fatigue, swelling)  |  |  |
| If Yes: The NYHA class of CHF: Class I Class II Class III Class IV  |

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| **It is recommended to continue current therapy** |  |  |

**If not, please indicate the corrected therapy in the table**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of drug  | Trade name | Daily dose | Yes | No |
| Beta-blockers **(bisoprolol)** |  |  |  |  |
| Preductal OD  |  |  |  |  |
| Long-acting nitrates  |  |  |  |  |
| Short-acting nitrates  |  |  |  |  |
| Calcium channel blockers  |  |  |  |  |
| Ivabradine  |  |  |  |  |
| ACE inhibitors |  |  |  |  |
| Sartans |  |  |  |  |
| Diuretics  |  |  |  |  |
| Antiplatelets |  |  |  |  |
| Lipid-lowering agents |  |  |  |  |
| Other drugs, including metabolic ones |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| Drugs for the treatment of concomitant pathology |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Assessment of treatment adherence**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Did you forget to take your medicine this morning? |  |  |
| Since the previous consultation, have you used all the reserve of your medicine? |  |  |
| Have you ever taken your medicine later than you usually intake it? |  |  |
| Has it ever happened that you did not take your medicine, because in some days you forgot about it? |  |  |
| Has it ever happened that you did not take your medicine, because on some days you felt that the medicine does more harm than good? |  |  |
| Do you think that you take too many tablets? |  |  |
| **SUM of Yes:** |  |  |
| **0 Yes** – good adherence; **1-2 Yes** – average adherence; **3 or more Yes** – non-adherence  |

**Quality of life assessment**

Please ask the patient to fill in a short questionnaire and a visual analogue scale (VAS) for assessing well-being in ***Appendix 1 (Visit 3)***.

**Assessment of adverse events**

In case of reporting the adverse events or special situations, please fill in the "Pharmacovigilance Form" (see ***Appendix 2***)

For serious events, the form must be completed and sent immediately. In other cases - within 2 working days.

**PLEASE ASK THE PATIENT TO RETURN THE SELF-MONITORING DIARY**

COMPLETION OF THE PROGRAM

If the program is completed, please indicate the reason:

1. Patient completed the program according to the plan

2. Patient prematurely terminated participation in the program on the \_\_\_\_\_\_\_\_ (specify the date)

Please specify below the MAIN (ONE) reason:

2.1. Decision of the patient (refusal of further participation) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.2. Decision of the doctor (the patient does not comply with the regimen of taking medications) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.3. Patient lost to follow-up \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.4. Adverse event \* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.5. Treatment failure \*

\* Please be sure to fill out the ***«Pharmacovigilance Form» (Appendix 2)***.

Appendix 1 visit 1

Quality of life assessment

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

**Mobility**

I have no problems in walking about 

I have some problems in walking about 

I am confined to bed 

**Self-Care**

I have no problems with self-care 

I have some problems with washing or dressing myself 

I am unable to wash or dress myself 

**Usual Activities** (*e.g. work, study, housework, family or leisure activities*)

I have no problems with performing my usual activities 

I have some problems with performing my usual activities 

I am unable to perform my usual activities 

**Pain / Discomfort**

I have no pain or discomfort 

I have moderate pain or discomfort 

I have extreme pain or discomfort 

**Anxiety / Depression**

I am not anxious or depressed 

I am moderately anxious or depressed 

I am extremely anxious or depressed



Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

Appendix 1 visit 2

Quality of life assessment

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

**Mobility**

I have no problems in walking about 

I have some problems in walking about 

I am confined to bed 

**Self-Care**

I have no problems with self-care 

I have some problems with washing or dressing myself 

I am unable to wash or dress myself 

**Usual Activities** (*e.g. work, study, housework, family or leisure activities*)

I have no problems with performing my usual activities 

I have some problems with performing my usual activities 

I am unable to perform my usual activities 

**Pain / Discomfort**

I have no pain or discomfort 

I have moderate pain or discomfort 

I have extreme pain or discomfort 

**Anxiety / Depression**

I am not anxious or depressed 

I am moderately anxious or depressed 

I am extremely anxious or depressed



Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

Appendix 1 visit 3

Quality of life assessment

 By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

**Mobility**

I have no problems in walking about 

I have some problems in walking about 

I am confined to bed 

**Self-Care**

I have no problems with self-care 

I have some problems with washing or dressing myself 

I am unable to wash or dress myself 

**Usual Activities** (*e.g. work, study, housework, family or leisure activities*)

I have no problems with performing my usual activities 

I have some problems with performing my usual activities 

I am unable to perform my usual activities 

**Pain / Discomfort**

I have no pain or discomfort 

I have moderate pain or discomfort 

I have extreme pain or discomfort 

**Anxiety / Depression**

I am not anxious or depressed 

I am moderately anxious or depressed 

I am extremely anxious or depressed



Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

## APPENDIX №2 Adverse event / Adverse drug reaction / Special situation\* PHARMA-FORM 0.32,3.0

|  |
| --- |
| **[**IC4-06795-051-RUS]*Please print and fax/e-mail immediately to the Local Servier Representative (see the address in the Local Protocol)* |
| **Year of birth or Age Gender Height Weight Patient number**|\_|\_|\_|\_| or |\_|\_|\_| M / F |\_|\_|\_| |\_|\_|\_| |\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|  |
| **Observed adverse event:** |  **Date of onset** |\_|\_| |\_|\_| |\_|\_|\_|\_| |  **Until (if recovered)**|\_|\_| |\_|\_| |\_|\_|\_|\_| |
|  |  |  |
| **Serious:**  No Yes, because: (please choose below)  Fatal Life-threatening  Hospitalisation or prolongation of hospitalisation  Persistent or significant disability or incapacity  Congenital anomaly/birth defect Medically significant | **Outcome:** Recovered  Recovered with sequelae Recovering  Not recovered Fatal  Unknown |
| **General disease(s) / Concomitant disease(s)** (please indicate year of first diagnoses) :  |
| **Course** (please enclose relevant findings e.g. laboratory, hospital reports, histology, etc.) : |
| **Causal relationship with the studied drug:**⁬ No  Yes Not applicable***If yes****, please specify dates of treatment with the studied drug in the table below on the first line:* ***If no or not applicable,*** *please indicate whether the adverse event /special situation is related to a Servier medicinal product (as mentioned in the following table)*: No  Yes *please specify which Servier medicinal product:* ………………………………. |
| **Medication list** | **Daily dosage /****application** | **Administered****from to** | **Indication** |
|  |  | **-** |  |
|  |  |  |  |
|  |  | **-** |  |
|  |  | **-** |  |
|  |  |  |  |
| Name of physician: StampSpeciality: Address:Phone: (stamp, if available) | Date:  Signature: |

*Special situations\*: situations where no adverse events occurred but information needs to be collected: exposure during pregnancy or breastfeeding, abuse, misuse, medication error, overdose, off label use, occupational exposure, lack of efficacy…*