Title: Specified Drug-Use Survey of Zafatek Tablets “Survey on long-term use in patients with type 2 diabetes mellitus”

NCT Number: NCT03555591

Protocol Approve Date: 25-Dec-2020

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Note; This document was translated into English as the language on original version was Japanese.

Protocol for Specified Drug-Use Survey of Zafatek Tablets "Survey on long-term use in patients with type 2 diabetes mellitus"

Survey Sponsor	**Takeda Pharmaceutical Company Limited**
Protocol Number	**Trelagliptin-5001**
Version Number	**Version 9**
Date of Preparation	**December 25, 2020**

Table of Contents

1.0 Background

Zafatek Tablets (hereinafter referred to as "this drug") is a dipeptidyl peptidase-4 (DPP-4) inhibitor. It contains trelagliptin succinate, and is orally administered once weekly for the treatment of type 2 diabetes mellitus. Since oral drugs to treat type 2 diabetes mellitus are usually used over a long time, the long-term use data in the routine clinical setting should be collected.

The present specified drug-use survey on "long-term use in patients with type 2 diabetes mellitus" (hereinafter referred to as "this survey") has been thus planned to investigate the long-term (3-year) safety and efficacy of this drug used in the routine clinical setting in type 2 diabetes mellitus patients.

This survey will be conducted in compliance with the Ministerial Ordinance on Good Post-Marketing Study Practice (GPSP) and relevant regulatory requirements.

2.0 Objectives

To evaluate the long-term safety and efficacy of this drug in patients with type 2 diabetes mellitus in the routine clinical setting in Japan.

3.0 Planned Sample Size and Rationale

3.1 Planned Sample Size

3,000 subjects

3.2 Rationale

Drugs to treat type 2 diabetes mellitus are likely used over a long time in the routine clinical setting. To investigate the long-term safety and efficacy of this drug used in the routine clinical setting, the observation period has been set to 3 years and the planned sample size has been set to 3000. With this sample size of 3000, adverse drug reactions occurring with an incidence of ≥0.1% can be detected with a probability of 95%.

Among the currently ongoing specified drug-use surveys of another DPP-4 inhibitor Nesina Tablets of "Survey on Nesina alone or with an alpha-GI", "Survey on Nesina with a thiazolidinedione", "Survey on Nesina with a sulfonylurea", and "Survey on Nesina with a biguanide", the safety analysis set as of April 15, 2015 consisted of 6734 subjects, of whom 52.5% were elderly, 54.4% had renal impairment, and 17.8% had hepatic impairment. Based on these data, the sample size of 3000 in this survey would allow data collection from approximately 1600 elderly patients, approximately 1600 patients with renal impairment, and approximately 500 patients with hepatic impairment. This sample size is not based on statistical power calculation.

4.0 Target Patient Population

This survey will be conducted in patients with type 2 diabetes mellitus who fulfill the following inclusion criteria and who do not meet the following exclusion criteria. The PRECAUTIONS section of the package insert for this drug should also be referenced.

4.1 Inclusion Criteria

Subjects should meet the following criterion:

Type 2 diabetes mellitus patients*

*: With or without use of antidiabetic medication

4.2 Exclusion Criteria

Subjects who meet any of the following criteria will be excluded:

(1) Have severe ketosis, diabetic coma or precoma, or type 1 diabetes mellitus
(2) Have severe infection, perioperative status, or serious trauma
(3) Have severe renal impairment or on dialysis due to end-stage renal disease
(4) Have a history of hypersensitivity to any ingredients of this drug

5.0 Dosage and Administration

The usual adult dosage of trelagliptin is 100 mg once weekly orally. The PRECAUTIONS section of the package insert for this drug should also be referenced.

<Precautions related to Dosage and Administration>

(1) **Patients with moderate renal impairment** will have increased blood concentrations of this drug because of delayed excretion, and thus require **dose reduction**, using the table below as a guide.

Dose in patients with moderate renal impairment

Serum creatinine (mg/dL)*	Creatinine clearance (Ccr, mL/min)	Dose
Male: >1.4 to ≤ 2.4 Female: >1.2 to ≤ 2.0	≥30 to <50	50 mg **once weekly**

*: Estimated values corresponding to the Ccr (for persons who are aged 60 years and weigh 65 kg)

(2) Patients must be instructed that:

1) Since this drug is designed for **once-weekly oral dosing**, this drug should be taken on the same day of every week.
2) If a missed dose is noticed, **only this dose** should be taken as soon as it is remembered, and the subsequent doses should be taken as originally scheduled.

6.0 Planned Number of Survey Sites by Specialty Department

Approximately 300 sites, including department of internal medicine

7.0 Methods

7.1 Duration of observation

36 months

7.2 Request for the Survey and Contract with the Medical Institution

This survey will use a web-based electronic data capture system (PostMaNet). To request the conduct of the survey, the person in charge at Takeda Pharmaceutical Company Limited (hereinafter referred to as "Takeda personnel") will explain to a potential survey physician and designee* about the survey objectives and contents, as well as the PostMaNet usage methods and handling of electronic signature and user IDs and passwords, using the "Request for cooperation in the specified drug-use survey", "Survey implementation outline", "Data entry screen images" and "PostMaNet User Manual (Quick Guide)". A written contract with the medical institution will then be signed, while the Takeda personnel will ask to perform the survey within the survey period specified on the contract.

*: The survey physician's designee must be a person who belongs to the medical institution (this includes a dispatched CRC or any other person with a signed consignment contract with the medical institution). Before the survey physician's designee can perform data entry to PostMaNet, the principal survey physician (ie, a person designated under contract at each survey site [medical institution or department] who is responsible for the conduct of the survey at the survey site) will prepare a written record (any format) of the designation and the date of designation and, after signing (or affixing name with seal), submit it to the Takeda personnel.

7.3 Patient Enrollment Method

Patients will be enrolled using a centralized registration method via PostMaNet. For patients prescribed this drug on or after the first day of the contract period for the medical institution, the survey physician will enter the patient data required for enrollment (see Section 9.1) into PostMaNet by 14 days after the prescription of this drug (with the day of prescription counted as "0 days" and the day following prescription counted as "1 day after prescription"), and enter an electronic signature.

7.4 Case Report Form (Electronic) Completion and Electronic Signature

The survey physician or designee will enter data on patient background, treatment details, etc. into PostMaNet, roughly within 1 month after the end of required observations at 12 months and 36 months after the start of treatment with this drug (or discontinuation of treatment), and the survey

physician will enter an electronic signature. If administration of this drug could not be confirmed, the fact of this should be entered (no other data are required).

For patients who discontinued treatment with this drug for certain reasons during the course of the observation period, the survey physician or designee will enter data on patient background, treatment details, etc. into PostMaNet roughly within 1 month after the end of required observations, and the survey physician will enter an electronic signature. However, for patients who discontinued treatment with this drug because of onset of an adverse event, even after the discontinuation of this drug the survey physician will continue observation as far as possible up to resolution or improvement of the adverse event. The survey physician or designee will then enter the observation result into PostMaNet, and the survey physician will enter an electronic signature.

7.5 Actions Taken for Serious Adverse Events

When any serious adverse event occurred during the observation period, the survey physician will immediately report it to the Takeda personnel. If requested by the Takeda personnel, the survey physician will also provide detailed information separately.

8.0 Planned Survey Period

Survey period: May 2016 to October 31, 2021

Patient enrollment period: May 2016 to October 31, 2018*

*: Even if this drug is prescribed by October 31, 2018, no patient enrollment (via PostMaNet) will be acceptable on or after November 1, 2018.

If the total number of patients enrolled in this survey reached the planned sample size before October 31, 2018, patient enrolment will be closed before the end of the patient enrollment period. If the patient enrollment period is shortened, the survey period will also be changed according to the shortened enrollment period.

9.0 Survey Variables

The survey physician or designee will enter data on the following variables into PostMaNet. The survey schedule is shown in Appendix.

9.1 Patient Enrollment

1) Survey variables

Date of prescription of this drug, subject identification number, patient initials, sex, date of birth, assessment against the inclusion criteria, assessment against the exclusion criteria, any serum creatinine data within 1 month before the start of treatment with this drug (presence or

absence and, if present, the specific data), severity of renal impairment and its basis (if without any serum creatinine data within 1 month before the start of treatment with this drug), any total bilirubin, AST or ALT data within 1 month before the start of treatment with this drug (presence or absence and, if present, the specific data), severity of hepatic impairment* and its basis (if without total bilirubin, AST or ALT data within 1 month before the start of treatment with this drug), presence or absence of concurrent or past history of pancreatitis or gallbladder stone

Severity of hepatic impairment	Mild	Moderate	Severe
Total bilirubin (mg/dL)	≥1.6 to <3.0	≥3.0 to <10	≥10
AST or ALT (U/L)	≥50 to <100	≥100 to <500	≥500
Manifestations	-	Jaundice, hepatomegaly, pain in the right hypochondrium, hepatic steatosis	Bleeding tendency, disturbed consciousness and other signs of hepatic failure (fulminant hepatitis), liver cirrhosis, liver tumor, persistent jaundice over ≥6 months

Adapted from Criteria for Seriousness/Severity Grading of Adverse Drug Reactions (Notification No. 80 of the Safety Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, dated June 29, 1992)

2) Time of data collection

At enrollment of the patient

9.2 Patient Background

1) Survey variables

Time of the diagnosis of type 2 diabetes mellitus, inpatient/outpatient category (at initiation of treatment with this drug), hypersensitive diathesis (presence or absence, and details), concurrent diseases (presence or absence, and details), medical history (presence or absence, and details), height, history of smoking, history of alcohol consumption

2) Time of data collection

At initiation of treatment with this drug

9.3 Treatment Details etc.

9.3.1 Treatment Details

1) Survey variables

Detailed use of this drug (dose, therapy dates, and reason for discontinuation), detailed use of concomitant drugs* (for the treatment of diabetes mellitus) (presence or absence, name of the drug, route of administration, daily dose, and therapy dates), detailed use of concomitant drugs (for other conditions than diabetes mellitus) (presence or absence, name of the drug, reason

for use, route of administration, daily dose, and therapy dates)

*Including antidiabetic medication discontinued within 3 months before use of this drug

2) Time of data collection

From initiation of treatment with this drug to 36 months later (or discontinuation of treatment)

9.3.2 Treatment Compliance Status, Treatment Noncompliance Details and Reasons, and Diet/Exercise Therapy Compliance Status

1) Survey variables

Status of treatment compliance with this drug*, treatment noncompliance details and reasons**, diet/exercise therapy compliance status***

*Treatment compliance status will be categorized as follows:

1. ≥90% of the doses were taken once weekly as prescribed.
2. ≥70% of the doses were taken once weekly as prescribed.
3. ≥50% of the doses were taken once weekly as prescribed.
4. <50% of the doses were taken once weekly as prescribed.
5. No doses were taken.
6. Unknown treatment compliance status

**Treatment noncompliance details and reasons (Only for patients who did not follow the once-weekly dosing schedule in any week)

a. Two doses were taken in any week.

<Reason>

A1: A missed dose was noticed and taken, and consequently two doses were taken in that week.

A2: Inadvertently two or more doses were taken in any week, for example because the scheduled dosing day in the week has slipped the mind.

A3: Inadvertently the dosing frequency was misunderstood as daily, and consequently two or more doses were taken in any week.

A4: Inadvertently this drug and daily medications were taken together, and consequently two or more doses of this drug were taken in any week.

A5: Other (Specify details.)

b. A larger dose than prescribed was taken.

The specific details and reason should be entered into PostMaNet.

c. There was any week in which no dose of this drug was taken.

<Reason>

A1: The dose was forgotten.

A2: The dose could not be taken because of conflicting work schedule etc.

A3: Other (Specify details.)

***Diet/exercise therapy compliance status will be categorized as follows:

1. ≥90% were performed (The prescribed regimen was nearly completely followed.)
2. ≥70% were performed (The prescribed regimen was followed most of the time.)
3. ≥50% were performed (The prescribed regimen was followed at least 50% of the time.)
4. <50% were performed (The prescribed regimen was followed less than 50% of the time)
5. Not performed
6. Unknown compliance status

2) Time of data collection

At initiation of treatment with this drug (only the diet/exercise therapy compliance status), and 1, 3, 6, 12, 18, 24, 30, and 36 months later (or discontinuation of treatment)

9.4 Items of Tests and Observations

9.4.1 Vital Signs

1) Items of tests and observations

Pulse rate, blood pressure (systolic /diastolic), body weight

2) Time of data collection

At initiation of treatment with this drug, and 1, 3, 6, 12, 18, 24, 30, and 36 months later (or discontinuation of treatment), if measured

9.4.2 Laboratory Tests

1) Test variables

HbA1c (NGSP value [same applies below]), fasting blood glucose, fasting insulin, fasting glucagon, fasting triglyceride, total cholesterol, HDL cholesterol, LDL cholesterol, serum creatinine, BUN, urinary albumin (urine albumin/creatinine ratio), AST, ALT, gamma-GTP, ALP, total bilirubin, amylase, lipase

2) Time of data collection

At initiation of treatment with this drug, and 1, 3, 6, 12, 18, 24, 30, and 36 months later (or discontinuation of treatment), if performed

9.4.3 Electrocardiogram

1) Test variables

Electrocardiogram (assessment and findings)

2) Time of data collection

At initiation of treatment with this drug, and 1, 3, 6, 12, 24, and 36 months later (or discontinuation of treatment), if performed

9.4.4 Waist Circumference and Testing Related to Coronary Arteries and Arteriosclerosis

1) Test variables

Waist circumference*, testing related to coronary arteries and arteriosclerosis** (eg, pulse wave velocity [PWV]), blood pressure pulse wave test [cardio-ankle vascular index; CAVI], cervical artery ultrasound, intravascular ultrasound [IVUS])

*: Measured at the patient's umbilicus level in a standing position at gentle exhalation. However, in patients with marked fat accumulation with downward deviation of the umbilicus, the waist circumference will be measured at the level of the midpoint between the lowest rib and the anterior superior iliac spine.

**: Any testing method is allowed, but in principle the same method should be used throughout the individual time points of evaluation. The testing may be omitted if no testing device is available.

2) Time of data collection

At initiation of treatment with this drug, and 6, 12, 24, and 36 months later (or discontinuation of treatment), if performed

9.4.5 Other Items of Observation

1) Observation item(s)

Presence or absence of pregnancy during the observation (only in women)

Any pregnancy found during the observation period should be immediately notified to the Takeda personnel. In response to a request by the Takeda personnel, the survey physician will provide detailed information (as far as possible up to the outcome of pregnancy, eg premature labour) using a Pregnancy Sheet separately.

2) Time of data collection

From initiation of treatment with this drug to 36 months later (or discontinuation of treatment)

9.5 Adverse Events

1) Survey variables

Presence or absence of adverse events (see Table 1), adverse event term, date of onset, seriousness and reason for the assessment as serious (see Table 2), reason for discontinuation of this drug, outcome assessment date, outcome, causal relationship to this drug* (see Table 3)

If the event outcome is "Not resolved" or "Unknown", and if the causal relationship is "Unassessable", the event should be followed as far as possible.

Detailed event information should be collected as much as possible for any reported adverse events of hypoglycemia, skin disorder, acute pancreatitis, proarrhythmia with prolonged QT/QTc interval, intestinal obstruction, infection, malignant tumor, and cardiovascular event (eg, symptomatic coronary artery disease, cerebrovascular disorder, arteriosclerosis obliterans,

cardiovascular death, sudden death); as well as any adverse events reported in patients with renal impairment, patients with hepatic impairment, elderly patients, patients on concomitant insulin, and patients given overdosage of this drug.

*: If the causal relationship to this drug is "Not related", the basis for the assessment should be collected.
If the causal relationship to this drug is "Unassessable", the reason should be collected.

Note) Special guidance about reporting of adverse events:
Abnormal worsening of the target disease, eg, outside the predictable range of the natural course of the disease, is regarded as an adverse event.

2) Time of data collection

From initiation of treatment with this drug to 36 months later (or discontinuation of treatment)

Table 1 Definition of an Adverse Event

An adverse event (AE) is defined as any untoward medical occurrence in a patient administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not the event is considered causally related to the use of the product. Note that the following events will also be handled as adverse events: - Any manifestation in an infant breastfed by the mother taking this drug - Any untoward manifestation in a child given this drug - Any manifestation due to vocational exposure to this drug - Any manifestation due to a counterfeit product of a prescription drug marketed by Takeda - Any untoward manifestation in a patient given this drug revealed by a lawsuit or any other legal action

Table 2 Criteria for Serious Adverse Events

An adverse event is assessed as "serious" if it results in any of the following outcomes: 1. results in death (Death), 2. is life-threatening (Life-threatening), 3. requires hospitalization or prolongation of existing hospitalization (Hospitalization/Prolongation of hospitalization), 4. results in persistent or significant disability/incapacity (Disability), 5. leads to a congenital anomaly or birth defect (Congenital anomaly), or 6. is any other important medical event that does not 1 to 5 above. Serious adverse events include events described in the "Takeda Medically Significant AE List". <u>Takeda Medically Significant AE List</u> - Acute respiratory failure/Acute respiratory distress syndrome (ARDS) - Anaphylactic shock - Torsade de pointes / Ventricular fibrillation / - Acute renal failure

Ventricular tachycardia - Malignant hypertension - Convulsive seizure (including convulsion and epilepsy) - Agranulocytosis - Aplastic anaemia - Toxic epidermal necrolysis / Oculomucocutaneous syndrome (Stevens-Johnson syndrome) - Hepatic necrosis - Acute hepatic failure	- Pulmonary hypertension - Pulmonary fibrosis (including interstitial pneumonia) - Neuroleptic malignant syndrome/ Malignant hyperthermia - Spontaneous abortion / Stillbirth and fetal death - Confirmed or suspected transmission of infectious agent by a medicinal product - Confirmed or suspected endotoxin shock

Table 3 Assessment of the Causal Relationship Between an Adverse Event and this Drug

Causality classification	Definition
Related	An adverse event that follows a temporal sequence from administration of this drug (including the course after withdrawal of the drug), or for which there is at least reasonable possibility of involvement of this drug and its causal role cannot be ruled out, although factors other than the drug, such as the primary disease, concurrent diseases, concomitant drugs or concurrent treatments, may also be responsible.
Not related	An adverse event that does not follow a temporal sequence from administration of this drug or that can reasonably be explained by other factors, such as the primary disease, concurrent diseases, concomitant drugs or concurrent treatments.
Unassessable	The causality cannot be assessed because of insufficiency of required information, such as temporal sequence of the event onset relative to administration of this drug (including the course after withdrawal of the drug), primary disease, concurrent diseases, concomitant drugs, and concurrent treatments.

10.0 Analytical Items and Methods

10.1 Statistical Analysis Plan

A statistical analysis plan will be prepared before the database lock. The statistical analysis plan will describe the definitions of evaluation items and details of analytical methods.

10.2 Analysis Populations

Two analysis populations of the “safety analysis set” and “efficacy analysis set” will be defined.

10.3 Disposition of Patients

Number of patients enrolled in the survey, number of patients with collected case report forms (electronic), numbers of patients evaluated for the safety and efficacy, number of patients excluded

from analyses and reasons for exclusion, etc. will be summarized.

10.4 Patient Background

Patient background data such as sex, age, duration of disease, hypersensitive diathesis, and concurrent diseases will be summarized.

10.5 Treatment Details etc.

Detailed use of this drug, treatment compliance status, detailed use of concomitant drugs, etc. will be summarized.

10.6 Safety Data

The following data will be summarized using the safety analysis set. Adverse events will be coded using the MedDRA/J, and summarized by Preferred Term (PT) and System Organ Class (SOC).

10.6.1 Adverse Event Profile

Adverse events occurring during the observation period will be summarized using frequency distribution by event type, causal relationship to this drug, etc.

10.6.2 Factors Likely Affecting the Safety

Adverse events and adverse drug reactions occurring during the observation period will be summarized using frequency distribution, with stratification of patients according to background factors (eg, sex, age) and treatment details (eg, detailed use of this drug, detailed use of concomitant drugs).

10.7 Efficacy Data

The following data will be summarized using the efficacy analysis set.

10.7.1 HbA1c Over Time

The HbA1c level and change (value at the respective time after initiation of treatment minus baseline value) at each time point of evaluation will be summarized. In addition, the glycemic control goal achievement rate at each time point of evaluation will be summarized.

10.7.2 Laboratory Test Values Over Time

For fasting blood glucose, fasting insulin, HOMA-β*, etc., the level and change at each time point of evaluation (value at the respective time after initiation of treatment minus baseline value) will be summarized.

* HOMA-β: (fasting insulin × 360)/(fasting blood glucose − 63)

10.7.3 Factors Likely Affecting the Efficacy

The change in HbA1c etc. will be summarized with stratification of patients according to background factors (eg, sex, age, baseline HbA1c level) and treatment details (eg, detailed use of this drug, detailed use of concomitant drugs).

10.8 Special Patient Populations

The safety and efficacy in patients with renal impairment, patients with hepatic impairment and elderly patients will be summarized with stratification of patients.

10.9 Interim Analysis

For early assessment and analysis of safety data from this survey, and publication of the results as necessary, an interim analysis will be performed based on the entered data up to 12 months of treatment, when the duration of observation has reached 1 year in all subjects.

11.0 Registration of Survey Information

Before initiation of this survey, information on this survey will be registered with the following website.

- Japan Pharmaceutical Information Center (JAPIC) Clinical Trials Information

12.0 Administrative Structure

12.1 Survey Manager

Post-marketing surveillance manager, Takeda Pharmaceutical Company Limited

13.0 Trustees

(1) AC Medical Inc.
Address: 1-12-38 Esaka-cho, Suita City, Osaka
Activities: Supportive activities in the PostMaNet construction

(2) Fujitsu Japan Corporation
Address: 2-2-2 Nakanoshima, Kita-ku, Osaka
Activities: PostMaNet construction and operation

(3) Cognizant Japan KK
Address: PMO Hanzomon, 2-1 Kojimachi, Chiyoda-ku, Tokyo
Activities: Data management

(4) PRA Health Sciences K.K.

Address: 4-1-3 Kyutaromachi, Chuo-ku, Osaka

Activities: Supportive activities in data management, record archiving, adverse event report conversion to PDF, and dissemination of information

(5) EPS Corporation

Address: 2-23 Shimomiyabicho, Shinjuku-ku, Tokyo

Activities: Statistical analysis activities

(6) PharField Corporation

Address: 2-8-20 Saga, Koto-ku, Tokyo

Activities: Monitoring progress management and monitoring activities

14.0 Other Necessary Items

14.1 Amendments to the Protocol

During the survey period, monitoring will be performed regarding the progress of the survey, occurrence of adverse drug reactions unexpected from the PRECAUTIONS and serious adverse drug reactions, any increase in the incidence of particular adverse drug reactions, validity of the survey variables, etc., and the protocol will be reviewed and amended as necessary. If any partial change to the DOSAGE AND ADMINISTRATION, INDICATIONS, etc. is approved during the survey period, whether or not the protocol should be amended will be examined, and the protocol will be amended as necessary.

14.2 Actions to be taken in Response to Detection of any Issues or Concerns

Whenever an issue is found regarding the safety or efficacy, the data will be investigated in detail, and necessary actions will be determined.

Appendix Observation Schedule

Survey variables \ Time of data collection		Observation period										
		Enrollment	Start of treatment	1 month	3 months	6 months	12 months	18 months	24 months	30 months	36 months	Discontinuation of treatment
Patient enrollment	Date of prescription of this drug	○										
	Subject identification number	○										
	Patient initials	○										
	Sex	○										
	Date of birth	○										
	Assessment against inclusion/exclusion criteria	○										
	Serum creatinine within 1 month before use of this drug (presence or absence and, if present, specific data)	○										
	Severity of renal impairment and its basis (if without any serum creatinine within 1 month before use of this drug)	○										
	Total bilirubin, AST or ALT within 1 month before use of this drug (presence or absence and, if present, specific data)	○										
	Severity of hepatic impairment and its basis (if without total bilirubin, AST or ALT within 1 month before use of this drug)	○										
	Presence or absence of concurrent or past history of pancreatitis or gallbladder stone	○										
Patient background	Time of the diagnosis of type 2 diabetes mellitus		○									
	Inpatient/outpatient category		○									
	Hypersensitive diathesis		○									
	Concurrent diseases		○									
	Medical history		○									
	Height		○									
	History of smoking		○									
	History of alcohol consumption		○									
Treatment details etc.	Detailed use of this drug		←○→									○
	Detailed use of concomitant drugs (for diabetes mellitus)		←○→				○*					○
	Detailed use of concomitant drugs (for other conditions than diabetes mellitus)		←○→				○					○
	Treatment compliance status, treatment noncompliance details and reasons			○	○	○	○	○	○	○	○	○
	Diet/exercise therapy compliance status		○	○	○	○	○	○	○	○	○	○
Assessments	Pulse rate, blood pressure, body weight		○	○	○	○	○	○	○	○	○	○
	Laboratory tests HbA1c, fasting blood glucose, fasting insulin, fasting glucagon, fasting triglyceride total cholesterol, HDL cholesterol, LDL cholesterol, serum creatinine, BUN, urinary albumin (urine albumin/creatinine ratio), AST, ALT, gamma-GTP, ALP, total bilirubin, amylase, lipase		○	○	○	○	○	○	○	○	○	○
	Electrocardiogram		○	○	○	○	○		○		○	○
	Waist circumference		○			○	○		○		○	○
	Testing related to coronary arteries and arteriosclerosis		○			○	○		○		○	○
	Any pregnancy (women only)		←○→				○					○
	Adverse event monitoring		←○→				○					○

○ : Performed

←○→ : Performed throughout the period

* Including antidiabetic medication discontinued within 3 months before use of this drug