TITLE PAGE

MYLAN

POST MARKETING OBSERVATIONAL STUDY PROTOCOL (DUPKST16002)

A SURVEY ON EFFICACY AND SAFETY IN PATIENTS WITH ENDOMETRIOSIS

Product Name:	Duphaston	
Type of Study:	Observational	
Date:	May 31, 2016	
CRO(s): (if applicable)	Name Address	Phone: Fax:
Biometrics: (if applicable)	Name Address	Phone Fax
Sponsor	Mylan	

This study will be conducted in compliance with this protocol.

Confidential Information

No use or disclosure outside Mylan is permitted without prior written authorization from Mylan.

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1 INTRODUCTION

Duphaston® Tablets have been used over a half century for the treatment of a wide range of indications in the field of gynecology and obstetrics, such as threatened miscarriage, habitual miscarriage, amenorrhea, irregular menstrual cycles (oligomenorrhea and hypermenorrhea), dysmenorrhea, dysfunctional uterine bleeding, infertility due to luteal insufficiency, endometriosis and so on, because the drug creates secretory endometrium similar to that by natural progesterone, exerts a potent effect to maintain pregnancy, forms a normal secretory endometrium, and has no effect to inhibit ovulation or elevate body temperature. As of April 30, 2010, Duphaston is approved overseas in 108 countries worldwide for various indications related to progesterone deficiency.

2 RATIONALE

In Japan, Duphaston® Tablets have appeared in 1965 for the treatment of endometriosis and been used at some medical institutions. However, after releasing of danazol in the early 1980's and gonadotropin-releasing hormone (GnRH) agonists in the late 1980's, pseudomenopause therapy became mainstream because of its high efficacy. However, pseudopregnancy therapy was recognized again due to adverse reactions associated with pseudomenopause therapy. After 2000, low-dose estrogen/progestin (LEP) combination drugs (as LEP products, ethinylestradiol/norethisterone combination drug and ethinylestradiol/drospirenone combination drug) and dienogest have been utilized as drugs that are safer and can be administered for a long time. In recent years, Duphaston® Tablets are increasing recognized again from the viewpoints of its efficacy and safety because the drug has no effect to inhibit ovulation or effect on basal body temperature, a diagnosis of ovulation and other conditions may be made by following up basal body temperature, and pregnancy may be achieved even during treatment with Duphaston[1)]. As previously mentioned, Duphaston® Tablets are an old drug, and there are only few clinical data from Japanese patients; thus, its latest clinical efficacy and safety data are being demanded again mainly by obstetrician-gynecologists.

3 STUDY OBJECTIVE

This survey is intended to collect efficacy and safety data of Duphaston® Tablets in patients with endometriosis under actual condition of its use and to obtain data for effectively and safely utilizing this drug. These evaluation and test results are assumed to provide useful information for assessing the contemporary significance of treatment with Duphaston® Tablets for endometriosis, ensuring the risk management (benefit-risk ratio) in patients treated with the drug and eventually examining disease control from the viewpoint of medical economy.

4 INVESTIGATIONAL PLAN

4.1 Selection of Study Population

4.1.1 Inclusion Criteria

The subjects of the survey will be patients with a diagnosis of "endometriosis," an indication of Duphaston® Tablets, who meet the following inclusion criteria.

(1) Women aged 20 to < 50 years

(2) Subjects with a chocolate cyst of the ovary measuring ≥ 3 cm in diameter on transvaginal ultrasonography at patient enrollment

(3) Subjects with a menstrual cycle of 25 to ≤ 38 days who ovulate and are confirmed to have normal menstruation at patient enrollment

4.1.2 Exclusion Criteria

Subjects corresponding to those who are listed in the CONTRAINDICATIONS or PRECAUTIONS Sections for Duphaston® Tablets as well as patients meeting the following exclusion criteria will not be included in the subjects of the survey.

(1) Subjects who used GnRH agonists within 6 months before patient enrollment

(2) Subjects who utilized hormone preparations containing corpus luteum hormone or estrogen as an active ingredient, low-dose contraceptive pills, middle-dose contraceptive pills, testosterone derivatives, or herbal products indicated for endometriosis within 3 months before patient enrollment

(3) Subjects who received surgical treatment for endometriosis such as transvaginal alcohol fixation, laparotomy or laparoscopic surgery within 2 months before patient enrollment

(4) Subjects who are pregnant or may possibly be pregnant at patient enrollment

(5) Subjects who are in breast feeding at patient enrollment

(6) Subjects who are determined by the investigator/subinvestigator to be not suitable for the subjects of the survey because of other reasons

[CONTRAINDICATIONS]

(1) Subjects with serious liver disorder or liver disease

(2) Subjects with known hypersensitivity to the active substance or to any of the excipients

(3) Subjects with known or suspected progestogen dependent neoplasms (e.g. meningioma)

(4) Subjects with undiagnosed vaginal bleeding

[PRECAUTIONS]

Careful Administration

(1) Subjects with a past or current history of heart or kidney disease

(2) Subjects with liver disorder

(3) Subjects with porphyria

(4) Subjects with depression

(5) Subjects with abnormal liver function values caused by acute or chronic liver disease

(6) Subjects with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucosegalactose malabsorption

4.2 Number of Patients to be Enrolled

Planned sample size of the survey: 65 patients

Rationale for setting:

Whether or not the size of chocolate cyst of the ovary reduced at the end of treatment from baseline will be evaluated using a sign test. When anticipated results would be a decrease-increase ratio of 7:3 and 10% of all patients being unchanged, a sample size was calculated to be 58 patients. Assuming a dropout rate of 10%, a necessary sample size of the survey would be 65 patients.

4.3 Investigator Selection Criteria

The survey will be conducted at approximately 12 sites including the department of gynecology and obstetrics, department of obstetrics, and department of gynecology.

4.4 Study Duration

Planned survey period: June 2016 to October 2017

Patient registration period: June 2016 to April 2017

4.5 Study Conduct

4.5.1 Product Supply

This study does not provide the product to perform it under the medical service under health insurance actual situation.

[DOSAGE AND ADMINISTRATION]

Usually for adults, 5 to 15 mg (1 to 3 tablets) as dydrogesterone per day should be orally administered in 1 to 3 divided doses. For endometriosis, 5 to 20 mg (1 to 4 tablets) per day should be orally administered.

<Recommended regimen>

In this survey, the following regimen is recommended:

Dydrogesterone 20 mg (4 tablets) per day should be orally administered in 2 divided doses (in the morning and evening). It should be administered for 21 days; dosage starts on the 5th day of each menstrual cycle until 25th day.

4.5.2 Description of Activities

(1) Request and contract for the survey

The survey will be performed at medical institutions where Duphaston is used and supplied. Survey personnel of Mylan EPD G.K. will provide an investigator/subinvestigator at the applicable medical institution with an adequate explanation on the objectives, subjects and methods of the survey. If the investigator/subinvestigator accepted to take part in the survey, Survey personnel of Mylan EPD G.K. shall take procedures for a contract. The contract shall be concluded in writing between the head of the medical institution and the person requesting the survey in Mylan EPD G.K.

(2) Survey method

This survey will be carried out using a central registration method and an electronic data capture (EDC) system. EDC system establishment and management are outsourced to Starsphere K.K.

(3) Registration method

(i) The investigator/subinvestigator will explain the details of the survey to a patient, obtain oral consent for participation in the survey from the patient, and record such a fact. The consent may be withdrawn at any time whether or not the survey has been undertaken.

(ii) In order to secure data entries and protect access, the investigator/subinvestigator will enter the name of an individual user and password to log in, and then make "patient registration" in the EDC system.

(iii) The patient should be registered within 14 days after the start of Duphaston treatment.

(iv) Information listed in Table 1 should be entered in the EDC system to register the patient.

(4) Cycle and observation period

(i) One cycle will consist of one menstruation cycle.

(ii) The observation period will be from the start of Duphaston treatment (cycle 1) to cycle 4.

(5) Input of patient information

The investigator/subinvestigator will enter information on all registered patients in the EDC system before the start of treatment, at the start of treatment (cycle 1), cycle 3 and after the completion of the observation period. If the treatment is discontinued, the investigator/subinvestigator will input information until the end day of treatment in the EDC system.

Table 1 List of Registration Items, Endpoints and Observation Time Points/Cycles

Registration Form/Case Report Form	Registration Form	Case Report Form					
Observation time points/cycles	At enrollment	Before treatment initiation	At treatment initiation (cycle 1)	Cycle 2	Cycle 3	Cycle 4	At the end of the observation period or at discontinuation
Registration information							
(1) Subject identification No.	○						
(2) Subject initials	○						
(3) Birth date or age	○						
(4) Planned start date of treatment	○						
(5) Oral consent	○						
Patient background characteristics							
(1) Diagnosis		○					
(2) Body height and weight		○					
(3) Pregnancy and lactation status		○					
(4) Menstruation and ovulation status		○					
(5) Complications		○					
(6) Past history		○					
(7) History of allergy		○					
(8) Serious hepatopathy or liver disease		○					
(9) Heart or kidney disease		○					
(10) History of drug treatment		○					
(11) History of surgical treatment		○					
Treatment compliance, clinical course and efficacy							
(1) Observation date (date of confirmation)		○	○		○		○
(2) Start date of treatment		○					
(3) Compliance with Duphaston treatment			○	◎	○	◎	○
(4) Measurement of ovarian chocolate cyst		○			○		○
(5) Severity of dysmenorrhea		○	○	◎	○	◎	○
(6) Use of analgesics		○	○	◎	○	◎	○
(7) VAS for dysmenorrhea		○	○	◎	○	◎	○
(8) Concomitant medications/therapies		○	○	◎	○	◎	○
(9) Date of withdrawal/dropout and its reason							○
Laboratory tests							
(1) Serum CA125		●					●
(2) Others		△					
Adverse events							
Adverse events		○					

One cycle will consist of one menstruation cycle.
Each endpoint will be observed in cycles marked with a symbol. Observation results should be entered in the EDC system.
○: Endpoint
◎: Investigate information on the next observation day, and enter it.
●: Perform the test during a non-menstruation period.
△: Enter information if observed.

5 ADVERSE EVENTS

5.1 Adverse Event Definition and Serious Adverse Event Categories

An adverse event (AE) is defined as any untoward medical occurrence in a patient administered a medicinal product, 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.

Adverse reactions are defined as a response to a medicinal product which is noxious and unintended. A Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility. Adverse reactions may arise from use of the product within or outside the terms of the marketing authorization or from occupational exposure. Conditions of use outside the marketing authorization include off-label use, overdose, misuse, abuse and medication errors.

Other pharmacovigilance relevant information is defined by the following.

- Intrauterine exposure (_____weeks of gestation)
- Lactational exposure
- Overdose
- Misuse
- Abuse
- Medication error
- Unexpected treatment effect
- Ineffectiveness
- Suspected pathogen infection to the drug
- Off-label use
- Occupational exposure

If an adverse event meets any of the following criteria, it is considered a **serious adverse event (SAE)**:

Death of Subject:	An event that results in the death of a subject.
Life-Threatening:	An event in which the patient was at risk of death at the time of the reaction; it does not refer to a reaction that hypothetically might have caused death if more severe.
Hospitalization:	An event that results in an admission to the hospital for any length of time. This does not include an emergency room visit or admission to an outpatient facility.
Prolongation of Hospitalization:	An event that occurs while the study subject is hospitalized and prolongs the subject's hospital stay.
Congenital Anomaly:	An anomaly detected at or after birth, or any anomaly that results in fetal loss.
Persistent or Significant Disability/Incapacity:	An event that results in a condition that substantially interferes with the activities of daily living of a study subject. Disability is not intended to include experiences of relatively minor medical significance such as headache, nausea, vomiting, diarrhea, influenza, and accidental trauma (e.g., sprained ankle).
Important Medical Event Requiring Medical or Surgical Intervention to Prevent Serious Outcome:	An important medical event that may not be immediately life-threatening or result in death or hospitalization, but based on medical judgment may jeopardize the subject and may require medical or surgical intervention to prevent any of the outcomes listed above (i.e., death of subject, life threatening, hospitalization, prolongation of hospitalization, congenital anomaly, or persistent or significant disability/incapacity). Additionally, any elective or spontaneous abortion or stillbirth is considered an important medical event. Examples of such events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

5.2 Severity

The physician will use the following definitions to rate the severity for any adverse event being collected as an endpoint/data point in the study and for all serious adverse events.

Mild:	The adverse event is transient and easily tolerated by the subject.
Moderate:	The adverse event causes the subject discomfort and interrupts the subject's usual activities.
Severe:	The adverse event causes considerable interference with the subject's usual activities and may be incapacitating or life threatening.

5.3 Relationship to Pharmaceutical Product

The investigator will use the following definitions to assess the relationship of the adverse event to the use of study drug:

Reasonable Possibility	An adverse event where there is evidence to suggest a causal relationship between the study drug and the adverse event.
No Reasonable Possibility	An adverse event where there is no evidence to suggest a causal relationship between the study drug and the adverse event.

If an investigator's opinion of no reasonable possibility of being related to study drug is given, an alternate etiology must be provided by the investigator for the adverse event.

5.4 All Adverse Events (including Serious Adverse Event) and Other Pharmacovigilance Relevant Information Collection Period

All adverse events and other pharmacovigilance relevant information during the survey will be collected during a period from the start of Duphaston treatment to the end of the observation period or discontinuation. All adverse events and other pharmacovigilance relevant information entered in the EDC system.

5.5 All Adverse Events (including Serious Adverse Event) and Other Pharmacovigilance Relevant Information Reporting

If all adverse events and other pharmacovigilance relevant information occurred, the investigator should enter in the EDC system. And the investigator has to report the form “notification of Adverse events” to the Affiliate Safety Representatives within 24 hours of becoming aware.

Affiliate Safety Representatives:
Safety Management Implementation Manager: Takao Miki
Address: 3-5-27 Mita, Minato-ku, Tokyo 108-6306
Tel: 03-4588-4492; Fax: 03-4588-4494

6 ETHICS AND QUALITY

(1) Ethics committee

This survey will be approved by the ethics committee of the medical institution.

(2) Registration of the Survey

This survey will be registered in the Clinical Trials.gov.

(3) Protocol revision

If new evidence is obtained during the period of the survey, the necessity for revising the protocol should be examined and, as necessary, revised. Also, when approval for partial changes in the dosage and administration or indications (excluding the case where a new reexamination period is designated) is received, the necessity for revising the protocol should be examined and, as necessary, revised.

(4) Measures when problems or questions arise

In the below mentioned cases, in order to detect or evaluate these factors and to demonstrate estimates made from the results of evaluation, the implementation of a new special drug use-results survey and/or postmarketing clinical study should be considered:

(i) When significant safety concerns such as the onset of serious and unknown ADRs are suggested

(ii) When the incidence of ADRs clearly increased

(iii) When any safety and efficacy problems as compared with pre-approval study results are identified

(5) Handling of information

(i) Information obtained from the survey shall be carefully managed based on the Personal Information Protection Law as paying full consideration to the sources of information and the privacy of patients.

(ii) Cases of ADRs reported which are notified to the Ministry of Health, Labour and Welfare may be disclosed as reported cases on the "Pharmaceuticals and Medical Devices Agency Homepage" of the Pharmaceuticals and Medical Devices Agency.

(6) Others

(i) Mylan EPD G.K. will pay expenses (expenses for the survey, management costs and overhead costs) for conducting the survey.

(ii) No person except for the investigators/subinvestigators may be involved in information obtained through the implementation of the survey because the EDC system will be used.

(iii) Data management and statistical analysis activities in the survey will be outsourced to third-party agencies specified in the Section "10. Name and Address of the Person to Whom the Activities Are Outsources, and Scope of the Outsourced Activities."

(iv) The conflict of interest in the survey will be properly managed to maintain fairness.

7 CASE REPORT FORMS

The following items (see Table 1) will be investigated and entered in the EDC system.

(1) Patient background characteristics

(i) Diagnosis, (ii) body height and weight, (iii) pregnancy and lactation status, (iv) menstruation and ovulation status, (v) complications, (vi) past history, (vii) history of allergy, (viii) serious hepatopathy or liver disease, (ix) heart or kidney disease, (x) history of drug treatment, (xi) history of surgical treatment

(2) Treatment compliance, clinical course and efficacy

(i) Observation date

- Observation days will be before the start of treatment, at the start of treatment (cycle 1), cycle 3 and at the completion of the observation period or at discontinuation.

(ii) Start date of treatment

(iii) Compliance with Duphaston treatment

- Verification of continuation

- Presence or absence of treatment interruption and the number of days of treatment interruption per cycle (approximate)
- Presence or absence of missed doses and the number of days with missed doses (approximate)

(iv) Measurement of ovarian chocolate cyst

- An ovarian chocolate cyst will be measured when a patient makes visits before the start of treatment, immediately after the end of cycle 3 and at the completion of the observation period or at discontinuation.
- In measurement of ovarian chocolate cyst, on a section visualizing the maximum diameter, two radial directions, namely the maximum diameter (D1) and maximum diameter (D2) orthogonal to D1, will be measured. Measured values (cm) will be rounded off to one decimal place and inputted.
- A chocolate cyst of the ovary will be deemed as a spheroid, and its volume will be calculated using the following formula: $[(D1 + D2) \times 1/2]^3 \times 0.52$ ($\pi = 3.1$). The volume will be rounded off to one decimal place.
- If there are two or more chocolate cysts of the ovary, similarly, two radial directions (D1 and D2) of each cyst will be measured and entered. Also, each of their volumes will be calculated in the same manner.
- When the directions of measurements before the start of treatment, cycle 3 and at the completion of the observation period or at treatment discontinuation vary because of reasons such as a chocolate cyst of the ovary cannot be clearly identified, the reason will be entered in the column for comments.
- For a chocolate cyst of the ovary newly confirmed during the treatment period, whether it is a cyst that has not been accidentally measured before treatment initiation or a new cyst will be inputted in the column for comments.
- For a chocolate cyst of the ovary that becomes difficult to identify during the treatment period, such a fact and its number will be entered in the column for comments.

(v) Severity of dysmenorrhea (dysmenorrhea severity score)

- The severity of dysmenorrhea will be assessed in accordance with Table 2, and a score will be entered. A dysmenorrhea score[2)] will be calculated using a total of the recorded score and a score for the use of analgesics.

(vi) Use of analgesics (including over-the-counter drugs) for the treatment of dysmenorrhea (score for the use of analgesics)

- The use of analgesics will be assessed in accordance with Table 3, and a score will be entered. A dysmenorrhea score will be calculated using a total of the recorded score and a dysmenorrhea severity score.

(vii) Visual analogue scale (VAS) for dysmenorrhea

- The VAS for dysmenorrhea will be assessed in accordance with Table 4. A length (cm) from the left end of the line (0) will be measured.
  Measured values (cm) will be rounded off to one decimal place and inputted.

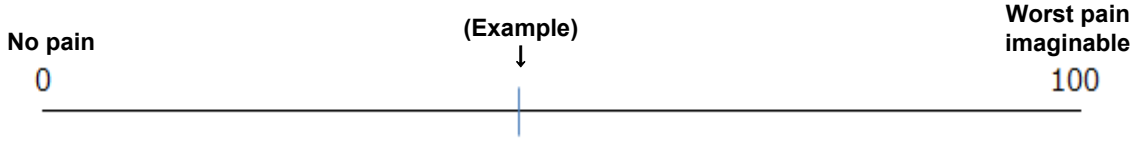
Table 2 Severity of dysmenorrhea

Severity of dysmenorrhea	Contents	Score
None	None	0
Mild	Rarely interfering with work (study and house work)	1
Moderate	Interfering with work (study and house work) requiring lying down to rest	2
Severe	Being confined to bed for ≥ 1 day, being unable to work (study and house work)	3

Table 3 Use of analgesics

Use of analgesics	Contents	Score
None	None	0
Mild	An analgesic was used for a day during the last (or current) menstruation period.	1
Moderate	An analgesic was used for 2 days during the last (or current) menstruation period.	2
Severe	An analgesic was used for ≥ 3 days during the last (or current) menstruation period.	3

Table 4 VAS for dysmenorrhea



(viii) Concomitant medications/therapies (If "yes," the name of a drug, daily dose, route of administration, reason for administration, start date of administration, end date of administration, name of concomitant therapy, reason for implementing concomitant therapy, start date of concomitant therapy, and end date of concomitant therapy will be inputted.)

(ix) Date of withdrawal/dropout and its reason

(3) Laboratory tests

(i) Serum CA125

- The test will be performed during a non-menstruation period, and the date of observation and test result will be entered.

(ii) Others

- If "yes" for other test items, observed details will be inputted.

(4) Adverse events and other pharmacovigilance relevant information

An adverse event (AE) is any unfavorable and unintended sign (including an abnormal laboratory value), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the drug. If an AE is noted, a follow-up investigation will be performed until it resolves whenever possible. AE information during the survey will be collected during a period from the start of Duphaston treatment to the end of the observation period or discontinuation.

If an AE (including an abnormal laboratory value) occurred, the following information should be entered:

- AE term
- Date of onset of AE
- Severity
- Seriousness
- Serious/non-serious
- Outcome
- Date of outcome
- Causal relationship with Duphaston
- Action for Duphaston
- If an abnormal change in a laboratory value is noted, the applicable laboratory value

If other pharmacovigilance relevant information occurred, it should be entered.
Other pharmacovigilance relevant information is defined by the following.

- Intrauterine exposure (____weeks of gestation)
- Lactational exposure
- Overdose
- Misuse
- Abuse
- Medication error
- Unexpected treatment effect
- Ineffectiveness
- Suspected pathogen infection to the drug
- Off-label use
- Occupational exposure

8 DATA ANALYSIS PLANS

8.1 In principle, the following items will be summarized and analyzed

(1) Matters concerning the disposition of patients

- Number of patients enrolled and number of patients whose case report forms (CRFs) are completed
- Numbers of patients analyzed for safety and efficacy
- Number of patients excluded from analysis and reasons for exclusion
- Date of withdrawal/dropout and their reasons

(2) Matters concerning safety

- Occurrence of AEs (e.g., types, severity and incidence of AEs)
- Occurrence of adverse drug reactions (ADRs) (e.g., types, severity and incidence of ADRs)

(3) Matters concerning efficacy

- Change in the volume of ovarian chocolate cyst (If there are two or more cysts, a total volume)

- Change over time in dysmenorrhea score (total of a dysmenorrhea severity score and a score for the use of analgesics)
- Change over time in VAS for dysmenorrhea
- Change in serum CA125

8.2 Analysis Methods

Statistical analyses are outsourced to Densuke Systems Co., Ltd.

Appropriate statistical procedures will be used according to the characteristics of the endpoint set.

9 FINAL REPORT AND PUBLICATIONS

Information collected from this survey will be used to notify information on proper use. In addition, collected information will be examined by a committee composed of the representatives of the investigators/subinvestigators and presented in papers or at academic conferences regardless of the details of information collected.

[Members composing the case review committee]

(1) Name: Jo Kitawaki

Affiliation: Professor, Department of Obstetrics and Gynecology, Kyoto Prefectural University of Medicine

(2) Name: Mikio Momoeda

Affiliation: Chief Director, Department of Integrated Women's Health, St. Luke's International Hospital

(3) Name: Kaori Koga

Affiliation: Associate Professor, Department of Obstetrics and Gynecology, Graduate School of Medicine and Faculty of Medicine, the University of Tokyo

10 REFERENCES

1) Mikio Momoeda. Treatment of dysmenorrhea associated with endometriosis (Chapter 8). Illustrated Series for Informed Consent. Iyaku Journal; 2015. p. 41-51.

2) Harada T, Momoeda M, Taketani Y, et al.: Low-dose oral contraceptive pill for dysmenorrhea associated with endometriosis: A placebo-controlled, double-blind, randomized trial. Fertil Steril 2008; 90: 1583-8.

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CLINICAL STUDY PROTOCOL (DUPKST16002)

A SURVEY ON EFFICACY AND SAFETY IN PATIENTS WITH ENDOMETRIOSIS

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