LOGO
FIELD ORGANIZATION

ZEG Berlin

INAS-VIPOS

International Active Surveillance Study of Medication Used for the Treatment of Endometriosis:
Visanne Post-approval Observational Study

– Baseline Questionnaire –

Country | Physician no. | Patient no. | ID

If you have any questions, please call our toll-free number: [telephone number].

To be filled in by the physician!

1. What is the name of the medication for endometriosis that you prescribed to your patient today? 1

_____

1a. If you prescribed an oral contraceptive today, have you prescribed an extended regimen? 2

☐ No ☐ Yes

2. Please tick the appropriate box to describe today's prescription: 3

☐ First-time hormonal prescription/no previous hormonal treatment

☐ Repeat of the same hormonal treatment after a medication break of at least 4 weeks

☐ Switching from another hormonal treatment without a relevant break (< 4 weeks)

☐ Switching from another hormonal treatment after a break of at least 4 weeks

3. How would you classify your patient's endometriosis? 4

☐ Diagnosis based only on clinical symptoms

☐ Endometriosis confirmed via surgery / laparoscopy

4. In the last 2 years, how many surgical procedures (diagnostic and/or therapeutical) has your patient received for the management of her endometriosis?

Number of surgical procedures: ⌊__⌋ 5

To be filled in by the study participant!

Personal Data

5. Please give your date of birth: D D (day) 6 | M M (month) 7 | Y Y Y Y (year) 8

6. What is your height? ⌊___⌋ 9 **cm**

7. What is your weight? ⌊___⌋ 10 **kg**

Gynecological History

8. How old were you when you had your first menstrual bleeding? ⌊__⌋ 11 **years**

9. Have you ever been pregnant? 12

☐ No → go to question 10 ☐ Yes

9a. If *yes*, when did you last give birth? D D (day) 13 | M M (month) 14 | Y Y Y Y (year) 15

9b. How many live births have you had? ⌊__⌋ 16

9c. How many abortions/miscarriages/still births have you had? ⌊__⌋ 17

Endometriosis

10a. When did you first experience endometriosis symptoms? M M (month) 18 | Y Y Y Y (year) 19

10b. When were you first diagnosed with endometriosis by a physician? M M (month) 20 | Y Y Y Y (year) 21

11. What symptoms do you have associated with your endometriosis? *(please tick all that apply)*

☐ Pelvic pain unrelated to period pain 22
☐ Experienced pain during or after sexual intercourse 23
☐ Difficulty conceiving/infertility 24
☐ Painful periods 25
☐ Heavy or irregular bleeding 26
☐ Pain when passing urine 27
☐ Pain during bowel movement 28
☐ Constipation or diarrhoea 29
☐ Tiredness / Weakness 30
☐ Other; which: 31 _____ 32

12. Have you had disabling pain associated with your endometriosis preventing you from working or attending social events <u>on least two days</u> in the last 4 weeks? 33

☐ No ☐ Yes

13. Please rate the pain associated with your endometriosis by marking the box that best describes your pain over the last 4 weeks, with 0 being no pain and 10 being unbearable pain. 34

no pain **0** **1** **2** **3** **4** **5** **6** **7** **8** **9** **10** unbearable pain

14. Have you had an operation to <u>diagnose and/or treat your endometriosis</u>? 35

☐ No → go on to question 15 ☐ Yes

If ***yes***, please list the operation (if known) and the date of the operation in the table below (i.e. excision of lesions, removal of ovarian cyst, hysterectomy, colonoscopy, keyhole surgery, diagnostic laparoscopy)
For additional space, use comment section on page 4.

Operation 36	**Date**
	M M month 37 Y Y Y Y year 38
	M M month Y Y Y Y year
	M M month Y Y Y Y year
	M M month Y Y Y Y year

15. Before today's prescription, have you been prescribed any other medication for <u>the treatment of endometriosis</u>? 39

☐ No → go on to question 16 ☐ Yes

If ***yes***, please list ***<u>all the prescribed medications</u>*** you have used in the ***<u>last 2 years</u>***. (i.e. prescribed pain killers, oral contraceptive, IUD, progestine, GnRH). Also give the duration of use (start and stop date). For additional space, use comment section on page 4.

Name (type) of medication 40	**from**	**to**
	M M month 41 Y Y Y Y year 42	M M month 43 Y Y Y Y year 44 ☐ ongoing 45
	M M month Y Y Y Y year	M M month Y Y Y Y year ☐ ongoing
	M M month Y Y Y Y year	M M month Y Y Y Y year ☐ ongoing
	M M month Y Y Y Y year	M M month Y Y Y Y year ☐ ongoing

Medication

16. Are you taking any other medication on a regular basis? (EXCLUDING today's prescription) 46

☐ No ☐ Yes, which one(s)? (please use Trade Name if known)

_____

_____ 47

17. Beyond today's prescribed medication, what are you currently doing to alleviate your endometriosis symptoms?

☐ Non-prescription pain killers 48
☐ Natural/herbal products 49
☐ Acupuncture 50
☐ Dietary modification 51
☐ Massage/manual therapy 52
☐ Home remedies (eg. hot water bottle) 53
☐ Nothing else 54
☐ Other; please specify 55 _____ 56

Medical History

18. Have you ever been told by a physician that you had or have any of the following diseases or conditions? Please also indicate whether this disease or condition was treated by a physician.

Deep venous thrombosis 57 (blood clot in the deep veins e.g. legs/arms)	☐ No	☐ Yes, in M M 58 month Y Y Y Y 59 year I was treated by a physician 60 ☐ Yes ☐ No I was treated with blood-thinning drugs 61 ☐ Yes ☐ No
Pulmonary embolism 62 (blood clot in the lung)	☐ No	☐ Yes, in M M 63 month Y Y Y Y 64 year I was treated by a physician 65 ☐ Yes ☐ No I was treated with blood-thinning drugs 66 ☐ Yes ☐ No
Myocardial infarction 67 (heart attack)	☐ No	☐ Yes, in M M 68 month Y Y Y Y 69 year I was treated by a physician 70 ☐ Yes ☐ No If yes, was an ECG performed? 71 ☐ Yes ☐ No Was the infarction confirmed by an ECG? 72 ☐ Yes ☐ No
Stroke 73	☐ No	☐ Yes, in M M 74 month Y Y Y Y 75 year I was treated by a physician 76 ☐ Yes ☐ No
Anemia 77	☐ No	☐ Yes, diagnosed in M M 78 month Y Y Y Y 79 year I was treated by a physician 80 ☐ Yes ☐ No I received a blood or iron trans-/infusion 81 ☐ Yes ☐ No I took iron tablets 82 ☐ Yes ☐ No
Depression requiring treatment 83	☐ No	☐ Yes, diagnosed in M M 84 month Y Y Y Y 85 year I was treated by a general practitioner 86 ☐ Yes ☐ No I was treated by a psychiatrist 87 ☐ Yes ☐ No I was admitted to hospital 88 ☐ Yes ☐ No There was a suicide attempt 89 ☐ Yes ☐ No
Cancer 90 (e.g. Breast cancer)	☐ No	☐ Yes, diagnosed in M M 91 month Y Y Y Y 92 year What kind of cancer? _____ 93 I was treated by a physician 94 ☐ Yes ☐ No
Other serious diseases 95 (e.g. hypertension, diabetes, benign tumor)	☐ No	☐ Yes, which? 1. _____ 96 When? M M 97 month Y Y Y Y 98 year I was treated by a physician 99 ☐ Yes ☐ No 2. _____ When? M M month Y Y Y Y year I was treated by a physician ☐ Yes ☐ No If you have had more than 2 serious diseases, please use the space in the comment section on page 4.
Operations 100 (excluding those listed in Q14)	☐ No	☐ Yes, I had operation(s), which? 1. _____ 101 When? M M 102 month Y Y Y Y 103 year 2. _____ When? M M month Y Y Y Y year If you have had more than 2 operations, please use the space in the comment section on page 4.

Relatives

19. Has your mother or sister(s) been diagnosed with endometriosis?

☐ None 104 ☐ Mother 105 ☐ Sister(s) 106

20. Have any of your parent(s) or sibling(s) been diagnosed with depression?

☐ None 107 ☐ Mother 108 ☐ Father 109 ☐ Sibling(s) 110

21. Have any of your parent(s) or sibling(s) ever had a deep venous thrombosis (blood clot) or pulmonary embolism (blood clot in the lung)?

☐ None 111 ☐ Mother 112 ☐ Father 113 ☐ Sibling(s) 114

Mood

22. We are interested in finding out about the impact of endometriosis and endometriosis treatment on your mood and whether this changes over the course of the study. Please answer these questions based on how you've felt over the last 4 weeks.

22a. Have you been feeling down, depressed or hopeless? 115

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

22b. Have you been feeling like you are a failure and have let down your friends and/or family? 116

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

22c. Have you felt happy or optimistic about the future? 117

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

Lifestyle

23. Do you regularly smoke cigarettes (at least one cigarette a day)? 118

☐ Yes — On average, how many cigarettes per day? ⌊__⌋ 119 Cigarettes

☐ No, stopped smoking — On average, how many cigarettes a day did you smoke in the past? ⌊__⌋ 119 Cigarettes

☐ No, never smoked regularly

Education

24. What is your most advanced school or college degree? 120

☐ No school-leaving certificate
☐ High school diploma
☐ Community college
☐ University / technical college

Please fill in today's date:

⌊D D⌋ day 121 ⌊M M⌋ month 122 ⌊2 0 Y Y⌋ year 123

Comment

Please tell us anything else you'd like us to know: 124

Thanks a lot for your help!