



**UCON Trial:**  
***Ulipristal versus Coil for the***  
***Management of Heavy Menstrual Bleeding***

## Follow-up Menstrual Blood Loss Diary

We would be most grateful if you could complete the enclosed diary during the course of your treatment.

**Please remember to post this back to Birmingham Clinical Trials Unit in the envelope provided.**

If you have any questions or need any help in answering the questions then please do not hesitate to contact:

Your local research nurse is XXXXXXXXXX and her phone number is XXXXXXXXXX  
Or you can call the UCON Trial Office on 0121 414 6665

All your answers will remain strictly confidential. Thank you for your participation in this study.

**Completed by participant:**

Date Completed:

D	D	-	M	M	M	-	Y	Y	Y	Y
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**Completed by UCON Trial Office:**

UCON Trial No.

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Patient Initials

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Date Sent:.....

D	D	-	M	M	M	-	Y	Y	Y	Y
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Date Form Entered:

D	D	-	M	M	M	-	Y	Y	Y	Y
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Follow-up Timepoint:

3 month

☐

6 month

☐

12 month

☐

Please would you record your preferred brand and absorbency of tampons and sanitary towels in the table below.

**e.g. Tampax – Super Plus days 1 – 2 then Tampax – Regular days 3 – 4**

Brand \_\_\_\_\_ and Type \_\_\_\_\_ of **towel** you used on days \_\_\_\_\_

Brand \_\_\_\_\_ and Type \_\_\_\_\_ of **towel** you used on days \_\_\_\_\_

Brand \_\_\_\_\_ and Type \_\_\_\_\_ of **tampon** you used on days \_\_\_\_\_



Brand \_\_\_\_\_ and Type \_\_\_\_\_ of **tampon** you used on days \_\_\_\_\_

**Table: Brand & Absorbency of Tampons and Sanitary Towels**

### Completing your Follow-Up Menstrual Loss Diary

On the next page you will find a Menstrual Blood Loss Diary. Please would you place a tick under the day and next to the box that represents how marked your sanitary materials are each time you change them. Please enter a tick each time you change your tampon or towel.

**For example:** on day 1 you use 6 tampons and 5 on day 2, you would mark the chart as follows:

Tampon	Day 1	Day 2	etc	etc
	✓✓✓✓✓✓	✓✓✓✓		
	✓✓✓	✓✓		

Record clots by indicating whether they are approximately 2 centimetres or for larger clots – approximately 3 centimetres.

**For example:** under day 1 you may say that you had 1 clot of approximately 2 centimetres and 3 clots approximately 3 centimetres. You would write this as 1 x 2cm, 3 x 3cm. Record any incidences of flooding by placing a tick mark in the flooding row under the relevant day.

**Please turn over for your daily blood loss diary**

**EVERYBODY PLEASE COMPLETE ON TREATMENT**

**Follow-Up Menstrual Blood Loss Diary**

Date of start of diary:

*As indicated in the enclosed letter*

-  -







Date Ulipristal Acetate Started:

-  -

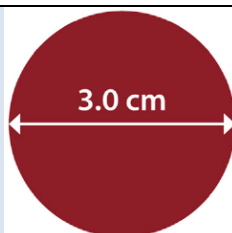
**OR**

Date LNG-IUS (Coil) fitted:

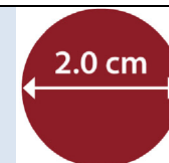
-  -

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
<b>Towels</b>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>
														
														
														
<b>Tampons</b>														
														
														
														
Small Clots / Flooding														
Large Clots / Flooding														







Large Clots / Flooding

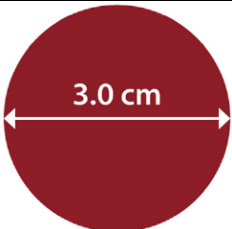
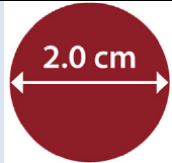


Small Clots / Flooding



Please continue diary with days 15 to 28 on the following page.....

	15	16	17	18	19	20	21	22	23	24	25	26	27	28
<b>Towels</b>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>
														
														
														
<b>Tampons</b>														
														
														
														
Small Clots / Flooding														
Large Clots / Flooding														

Large Clots / Flooding		Small Clots / Flooding	
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References:

Higham JM, O'Brien PM, Shaw RW. Assessment of menstrual blood loss using a pictorial chart. *Br J Obstet Gynaecol.* 1990;97(8):734-9.

Donnez J, Hudecek R, Donnez O, Matule D, Arhndt HJ, Zatik J, Kasilovskiene Z, Dumitrascu MC, Fernandez H, Barlow DH, Bouchard P, Fauser BCJM, Bestel E, Terrill P, Osterloh I, Loumaye E. Efficacy and safety of repeated use of ulipristal acetate in uterine fibroids. *Fertility and Sterility.* 2015; 103, (2), 519-527.e3

**UPA GROUP ONLY PLEASE COMPLETE OFF TREATMENT**

**Follow-up Menstrual Blood Loss Diary**

Date Ulipristal Acetate Stopped: 

D	D
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M	M	M
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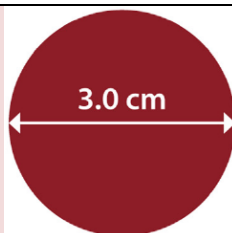
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Y	Y	Y	Y
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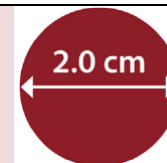
 Please start on first day that you are not taking treatment and complete every day for 28 days.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
<b>Towels</b>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>
														
														
														
<b>Tampons</b>														
														
														
														
Small Clots / Flooding														
Large Clots / Flooding														







Large Clots / Flooding

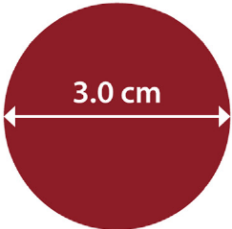
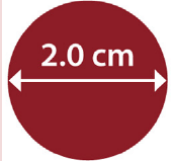


Small Clots / Flooding



Please continue diary with days 15 to 28 on the following page.....

	15	16	17	18	19	20	21	22	23	24	25	26	27	28
<b>Towels</b>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>	No bleeding <input type="checkbox"/>
														
														
														
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Small Clots / Flooding														
Large Clots / Flooding														

Large Clots / Flooding		Small Clots / Flooding	
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EudraCT Number: 2014-003408-65

Version 3.0 – 24<sup>th</sup> February 2016

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