

Introducing a monthly diary and questionnaire to chart your treatment progress

The information contained in this educational resource is intended to reinforce and supplement information you receive from your healthcare team. It is not a substitute for medical advice from your physician. If you have questions about the information you read in this educational resource, please discuss them with your healthcare provider.

This has been produced as a patient education resource by Pfizer Inc.



## My UC SYMPTOM TRACKER

#### The Symptom Tracker: A Tool to Support UC Disease Management

Living with ulcerative colitis (UC) can be difficult.<sup>1,2</sup> Not only must patients deal with the physical problems caused by UC, they also face potentially uncomfortable situations when trying to discuss sometimes severe and often embarrassing symptoms with their healthcare professional (HCP).<sup>3</sup>

Yet active communication and cooperation between patients and HCPs are important in treating UC.<sup>2</sup> Some patients may not always communicate the range of concerns they have about their condition.<sup>3</sup> At the same time, some HCPs may not always recognize the full effect UC is having on their patients' everyday lives.<sup>4</sup>

Improving the communication you have with your gastroenterologist and other HCPs is what this workbook is all about. Another goal of this tool is to encourage patient empowerment. This is a process that helps you gain control over your health and act on medical issues that you define as important.

*My UC Symptom Tracker* is designed to help you record important information about your UC. The measurement tools provided on the following pages are based on a research instrument used in clinical studies.<sup>5</sup> That research instrument has been adapted for patients' use. As the *UC Symptom Tracker*, it helps you monitor specific UC symptoms that you may have on a daily basis.

Above all, this workbook may help you advance your own care through improved communication with your HCP. By recording your symptoms—and regularly discussing them with your HCP team—you may help advance your ongoing disease management for UC.

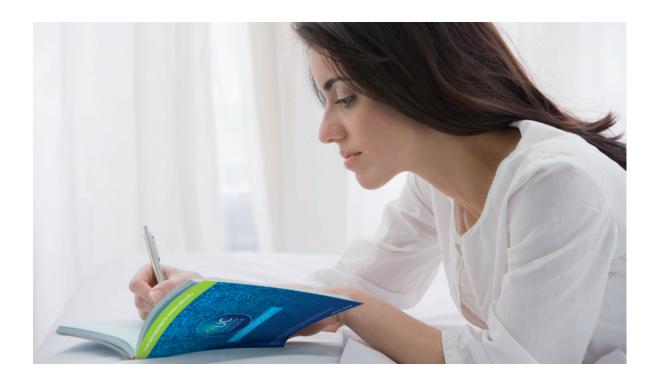
#### The Importance of Tracking Your UC Symptoms and Supporting Your Own Disease Management Plan

UC is a chronic, inflammatory disease of the colon and rectum with 2 key defining symptoms: increased stool frequency and bloody diarrhea (with or without mucus).<sup>6</sup> Chronic means that the signs and symptoms of UC tend to come and go with fairly long periods in between flares.<sup>7</sup> Flares are cases where UC symptoms return after they have been absent.<sup>8</sup> Inflammatory means that UC is marked by reddened, swollen tissue.<sup>9</sup> These and other signs of UC tend to alternate between periods of relapse and remission. Remission refers to the situation where UC symptoms have been resolved.

Your HCP needs to know how severe your UC symptoms are and the patterns of the disease you are experiencing. Understanding how and when UC symptoms occur in your body—as well as how the condition may affect your overall quality of life—can help your HCP address your individual needs.

Here is where the UC Symptom Tracker may assist you with monitoring your UC symptoms.

This workbook contains 2 types of forms: a monthly diary to record your UC symptoms and a questionnaire about how UC is affecting your quality of life. Together, they create an important tool to help you recall any specific issues, thoughts, or concerns you have about your UC and which you'll want to discuss with your HCP at your next office visit.



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#### The Mayo Score: A Clinical Assessment Tool

The Mayo Score is a common way to measure the level of disease activity in UC.<sup>5</sup> The UC Symptom Tracker is based on the Mayo Score.

The full Mayo Score combines patient-provided information with the findings of an endoscopy a procedure in which your healthcare professional (HCP) examines the inside of your body using a lighted instrument.<sup>10,11</sup> An HCP performs an endoscopy for diagnosing UC or assessing vour current condition.<sup>12</sup>

Four factors are cited in a full Mayo Score assessment<sup>10,11</sup>:



Rectal bleeding

Findings of the endoscopy

The physician's overall assessment of a patient's disease severity

HCPs measure factors 3 and 4. But you can help assess your UC by tracking the first 2 items on the UC Symptom Tracker: stool frequency and rectal bleeding.

The UC Symptom Tracker is derived from the full 12-point Mayo score. Another modified scale used by some clinicians is the 9-point (or partial) Mayo score.<sup>13</sup>

	Findings on Endoscopy	Physician Global Assessment of Disease Activity	Stool Frequency	Rectal Bleeding
Full 12-point Mayo Score	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
9-point (partial) Mayo Score		$\checkmark$	$\checkmark$	$\checkmark$
UC Symptom Tracker Score			$\checkmark$	$\checkmark$

#### Completing Your UC Symptom Tracker

The UC Symptom Tracker represents a patient-reported outcome (PRO) measurement that offers vital information for decision-making.<sup>14</sup>

The UC Symptom Tracker diary provides forms that enable you and your doctor to:

- Track your stool frequency
- Monitor and assess your level of rectal bleeding

There are no set criteria for how often you should fill out the diary forms. However, it is advisable to begin completing the forms on the day you receive this workbook.

After you record your first entry, it is up to you how often you enter information on the UC Symptom *Tracker* forms. Remember, the more information you can provide regularly to your HCP about your symptoms, the more he or she can effectively evaluate your progress.



While there may be differing opinions about the ultimate goal of UC therapy, most HCPs would agree that a lack of or reduced bleeding and low stool frequency are goals that will help you maintain a sense of well-being and help minimize effects on your quality of life.<sup>1,15</sup>

#### Measuring Your Level of Fatigue

The UC Symptom Tracker diary forms also ask you to evaluate any fatigue you may be experiencing. Fatigue is common among patients with UC.<sup>6</sup> This may be due to general disease activity, as well as blood loss (eq, from rectal bleeding), which can lead to anemia.<sup>17</sup> Blood loss in stool is monitored through lab tests for iron levels, hemoglobin, and hematocrit (Hgb/HCT).<sup>18</sup>

#### **Completing the Quality-of-Life Questions**

Each month—and before each office visit with your HCP—consider how UC may have been affecting your personal and work life. Using questions adapted from the Colorectal Functional Outcome Questionnaire (COREFO) and the Short Inflammatory Bowel Disease Questionnaire (SIBDQ), the workbook lets you note important lifestyle-related challenges posed by your UC.<sup>19,20</sup> Combined with the information on stool frequency and rectal bleeding—tracked by calendar and time-of-day entries-this input may help your HCP understand your current level of disease activity.

#### What Your Numbers Mean

The UC Symptom Tracker is designed to help you:

- Monitor improvement or worsening in your stool
- frequency and rectal bleeding as a way to keep track
- of your response and how your disease management plan is working
- Identify an indication of a potential flare

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#### Completing the UC Symptom Tracker Diary

My personal targets, as determined by my healthcare professional (see page 13)				My baseline average number of stools when feeling well		
	Stool Frequency		Rectal Bleeding		(Note: everyone's average stool frequency is different)	

**Rectal Bleeding Score**<sup>5</sup> (Place corresponding number in box on calendar day b

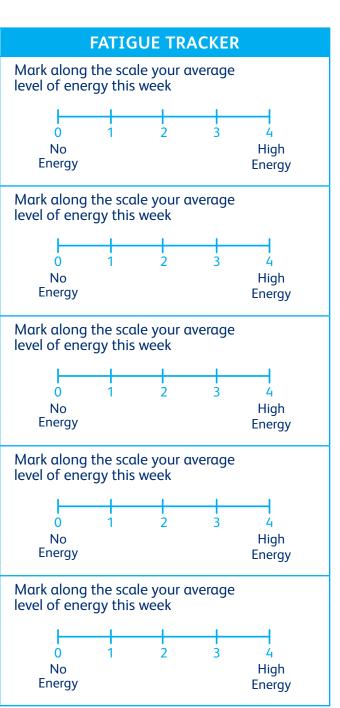
None	Visible blood	Visible blood	
	with stool less than half the	with stool half of the time or	Passing I alon
	time	more	
0	1	2	3

MONTH 1	MONTH 2	MONT	Н 3				
	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No)ª							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
Total Number of Stools							
Rectal Bleeding Score							

<sup>a</sup>Stools at night refers to bowel movements that wake you up after you have gone to bed and before you get up in the morning to start your day.

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#### Completing the UC Symptom Tracker Diary

My personal targets, o healthcare profession		My baseline average number of stools when feeling well
Stool Frequency	Rectal Bleeding	(Note: everyone's average stool frequency is different)

#### **Rectal Bleeding Score<sup>5</sup>**

(Place corresponding number in box on calendar day b

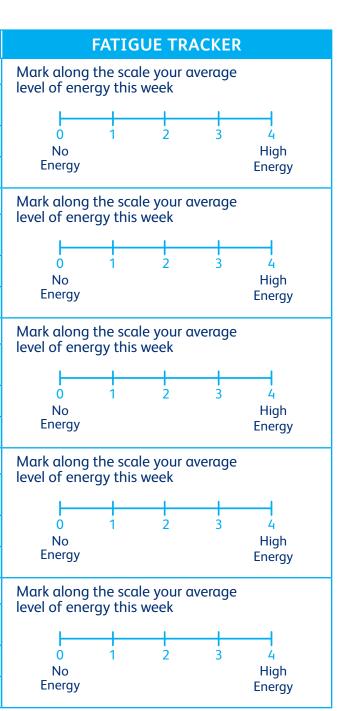
None	Visible blood	Visible blood	
	with stool less	with stool half	Passing I
	than half the	of the time or	alon
	time	more	
0	1	2	3

MONTH 1	MONTH 2	MONT	Н 3				
	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No)ª							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No)ª							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
Total Number of Stools							
Rectal Bleeding Score							

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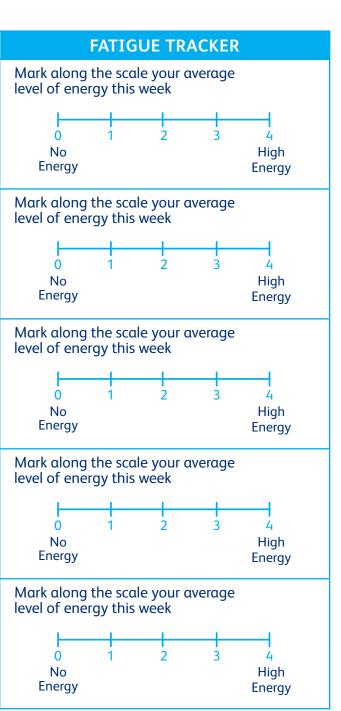
None	Visible blood with stool less than half the time	Visible blood with stool half of the time or more	Passing t alone
0	1	2	3

MONTH 1	MONTH 2	MONT	ТН З				
	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
Total Number of Stools							
Rectal Bleeding Score							
	Date	Date	Date	Date	Date	Date	Date
Stools at Night (Write Yes or No) <sup>a</sup>							
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#### Completing the Quality of Life Questionnaire<sup>a</sup>

Answer the questions below to help assess how UC may be affecting your daily activities and other aspects of your life. Complete this guestionnaire monthly and right before your scheduled doctor's office visit. The questions relate to the symptoms you are having as a result of your UC.

و مع					DAY
		MONTH 1	MONTH 2	MONTH 3	BEFORE OFFICE
					VISIT
1	How often during the <b>previous week</b> have you had to delay or cancel a social engagement because of your ulcerative colitis? <sup>20</sup>				
	All of the time				
	Some of the time				
	Hardly any of the time				
	None of the time				
2	How much of the time during the <b>previous week</b> have you felt upset because of your ulcerative colitis? <sup>20</sup>				
	All of the time				
	Some of the time				
	Hardly any of the time				
	None of the time				
3	How much difficulty have you had, as a result of your ulcerative colitis, doing leisure or sports activities you would have liked to have done during the <b>previous week</b> ? <sup>20</sup>				
	A lot of difficulty				
	Some difficulty				
	Hardly any difficulty				
	No difficulty; my ulcerative colitis symptoms did not limit participation in sports or leisure activities				
4	In the <b>previous 2 weeks</b> , how often do you soil your underwear (soiling from the bowel)? <sup>19</sup>				
	Never				
	Less than once a week				
	1-2 days per week				
	3-5 days per week				
	6-7 days per week				
5	In the <b>previous 2 weeks</b> , if you needed to go urgently, did you have trouble stopping your bowel movement for longer than 15 minutes? <sup>19</sup>				
	Yes				
	No				
	I don't know				

#### HCP=healthcare professional

<sup>a</sup>Questions adapted from the Colorectal Functional Outcome Questionnaire and the Short Inflammatory Bowel Disease Questionnaire.<sup>19,20</sup> Reprinted by permission from Springer-Verlag: Bakx R, Sprangers MA, Oort FJ, et al. Development and validation of a colorectal functional outcome questionnaire. Int J Colorectal Dis. 2005;20(2):126-136; Copyright 2005.<sup>19</sup>

Use of the Inflammatory Bowel Disease Questionnaire, authored by Dr. Jan Irvine et al., was made under license from McMaster University Hamilton, Canada.<sup>20</sup>

### **Preparing for Your Next Appointment With Your Healthcare Professional (HCP)**

Your next appointment:	
НСР	
Date	Arriva
Location	

#### **4 Suggested Questions for Your Doctor**



**Stool Frequency** 



3

Based on my recent scores, do you feel my UC is under control?

At what levels-eg, specific measurements of stool frequency and rectal bleedingshould I consider my situation serious enough to call you?

like me to track? • • • •

List any other questions, issues, or concerns you would like to discuss with your HCP (gastroenterologist, nurse practitioner, physician assistant, or pharmacist) during your next visit:

1	
2	
3	

#### **Available Resources**

The American College of Gastroenterology www.gi.org

The American Gastroenterological Association www.gastro.org

**Crohn's and Colitis Foundation** www.crohnscolitisfoundation.org al Time

#### **Rectal Bleeding**

Besides my current stool frequency/rectal bleeding measurements, fatigue, and 4 quality-of-life questions, are there any other physical or lifestyle factors you would

### Notes

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References: 1. Bernstein CN, Eliakim A, Fedail S, et al. World Gastroenterology Organisation Global Guidelines Inflammatory Bowel Disease: Update August 2015. J Clin Gastroenterol. 2016;50(10):803-818. 2. Greene J, Hibbard JH. Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. J Gen Intern Med. 2012;27(5):520-526. 3. Lönnfors S, Vermeire S, Greco M, Hommes D, Bell C, Avedano L. IBD and health-related quality of life - discovering the true impact. J Crohns Colitis. 2014;8(10):1281-1286. 4. Schreiber S, Panés J, Louis E, Holley D, Buch M, Paridaens K. Perception gaps between patients with ulcerative colitis and healthcare professionals: an online survey. BMC Gastroenterol. 2012;12:108. 5. Lewis JD, Chuai S, Nessel L, Lichtenstein GR, Aberra FN, Ellenberg JH. Use of the noninvasive components of the Mayo score to assess clinical response in ulcerative colitis. Inflamm Bowel Dis. 2008;14(12):1660-1666. 6. Danese S, Fiocchi C. Ulcerative colitis. N Engl J Med. 2011;365(18):1713-1725. 7. Crohn's and Colitis Foundation website. What is ulcerative colitis? http://www.crohnscolitisfoundation.org/what-are-crohns-and-colitis/ what-is-ulcerative-colitis/. Accessed April 8, 2021. 8. Crohn's and Colitis Foundation website. Managing Flares and IBD Symptoms. https://www.crohnscolitisfoundation.org/sites/default/files/2019-07/managing-flares-brochure-final-online.pdf. Accessed March 27, 2021. 9. Ungaro R, Mehandru S, Allen PB, Peyrin-Biroulet L, Colombel JF. Ulcerative colitis. Lancet. 2017;389(10080):1756-1770. 10. Paine ER. Colonoscopic evaluation in ulcerative colitis. Gastroenterol Rep (Oxf). 2014;2(3):161-168. 11. Schroeder KW, Tremaine WJ, Ilstrup DM. Coated oral 5-aminosalicylic acid therapy for mildly to moderately active ulcerative colitis. A randomized study. N Engl J Med. 1987;317(26):1625-1629. 12. Rameshshanker R, Arebi N. Endoscopy in inflammatory bowel disease when and why. World J Gastrointest Endosc. 2012;4(6):201-211. 13. Bewtra M, Brensinger CM, Tomov VT, et al. An optimized patient-reported ulcerative colitis disease activity measure derived from the Mayo Score and the simple clinical colitis activity index. Inflamm Bowel Dis. 2014;20(6):1070-1078. 14. Bojic D, Bodger K, Travis S. Patient reported outcome measures (PROMs) in inflammatory bowel disease: new data. J Crohns Colitis. 2017;11 (suppl 2):S576-S585. 15. Magro F, Gionchetti P, Eliakim R, et al. Third European evidence-based consensus on diagnosis and management of ulcerative colitis. part 1: definitions, diagnosis, extra-intestinal manifestations, pregnancy, cancer surveillance, surgery, and ileo-anal pouch disorders. J Crohns Colitis. 2017;(6)649-970. 16. Jonefjäll B, Simrén M, Lasson A, Öhman L, Strid H. Psychological distress, iron deficiency, active disease and female gender are independent risk factors for fatigue in patients with ulcerative colitis. United European Gastroenterol. 2018;6(1):148-158. 17. Niepel D, Klag T, Malek NP, Wehkamp J. Practical guidance for the management of iron deficiency in patients with inflammatory bowel disease. Ther Adv Gastroenterol. 2018;11:1756284818769074. 18. Mayo Clinic website. Complete blood count (CBC). https://www.mayoclinic.org/tests-procedures/complete-blood-count/about/pac-20384919. Accessed April 8, 2021. 19. Bakx R, Sprangers MA, Oort FJ, et al. Development and validation of a colorectal functional outcome guestionnaire. Int J Colorectal Dis. 2005;20(2):126-136. 20. Irvine EJ, Zhou Q, Thompson AK. The Short Inflammatory Bowel Disease Questionnaire: a quality of life instrument for community physicians managing inflammatory bowel disease. CCRPT Investigators. Canadian Crohn's Relapse Prevention Trial. Am J Gastroenterol. 1996;91(8):1571-1578.