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eCOA Screen Report Evidera

**Sponsor: Takeda
Protocol: TAK-906-2002**

Document Version: 1.0



**Takeda TAK-906-2002
eCOA Screen Report, Version 1.0**

© YPrime 2017 16-JUN-2017 01:38 PM Subject Main Menu	© YPrime 2018 24-JUL-2018 12:46 PM Daily Symptom Diary
<p>Welcome to your diary.</p> <div><div>Daily Symptom Diary</div><div><input type="checkbox"/> START</div></div> <div></div> <div><div>Training </div><div>Sync Data </div><div>Log Out </div></div>	<p>Instructions: The following questions ask about bloating severity you may have each day.</p> <p>Please complete the Bloating Severity Scale at about the same time every evening.</p> <p>For the bloating symptom, please <u>select the answer</u> that best describes the <u>worst severity</u> of bloating <u>during the past 24 hours</u>. Please be sure to answer each question.</p> <div><div>< Back</div><div>Next ></div></div>



© YPrime 2018 Daily Symptom Diary	23-JUL-2018 01:37 PM© YPrime 2018 Daily Symptom Diary	24-JUL-2018 12:47 PM					
<p>Please select the answer that best describes the <u>worst severity</u> of this symptom <u>during the past 24 hours</u>.</p> <p>Bloating (feeling like you need to loosen your clothes)</p> <table border="1"><tr><td>None</td></tr><tr><td>Mild</td></tr><tr><td>Moderate</td></tr><tr><td>Severe</td></tr><tr><td>Very Severe</td></tr></table>	None	Mild	Moderate	Severe	Very Severe	<p>Instructions: The following questions ask about symptoms you may have each day.</p> <p>Please complete the daily diary at about the same time every evening.</p> <p>For each symptom, please <u>select the answer</u> that best describes the <u>worst severity</u> of each symptom <u>during the past 24 hours</u>. Please be sure to answer each question.</p>	
None							
Mild							
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Severe							
Very Severe							
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© YPrime 2018 23-JUL-2018 01:38 PM© YPrime 2018 23-JUL-2018 01:38 PM											
Daily Symptom Diary	Daily Symptom Diary										
<p>Please select the answer that best describes the <u>worst severity</u> of this symptom <u>during the past 24 hours</u>.</p> <p>1. Nausea (feeling sick to your stomach as if you were going to vomit or throw up)</p> <table><tr><td>None</td></tr><tr><td>Mild</td></tr><tr><td>Moderate</td></tr><tr><td>Severe</td></tr><tr><td>Very Severe</td></tr></table>	None	Mild	Moderate	Severe	Very Severe	<p>Please select the answer that best describes the <u>worst severity</u> of this symptom <u>during the past 24 hours</u>.</p> <p>2. Not able to finish a normal-sized meal (for a healthy person)</p> <table><tr><td>None</td></tr><tr><td>Mild</td></tr><tr><td>Moderate</td></tr><tr><td>Severe</td></tr><tr><td>Very Severe</td></tr></table>	None	Mild	Moderate	Severe	Very Severe
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© YPrime 2018 23-JUL-2018 01:38 PM© YPrime 2018 23-JUL-2018 01:38 PM											
Daily Symptom Diary	Daily Symptom Diary										
<p>Please select the answer that best describes the <u>worst severity</u> of this symptom <u>during the past 24 hours</u>.</p> <p>3. Feeling excessively full after meals</p> <table><tr><td>None</td></tr><tr><td>Mild</td></tr><tr><td>Moderate</td></tr><tr><td>Severe</td></tr><tr><td>Very Severe</td></tr></table>	None	Mild	Moderate	Severe	Very Severe	<p>Please select the answer that best describes the <u>worst severity</u> of this symptom <u>during the past 24 hours</u>.</p> <p>4. Upper abdominal pain (above the navel)</p> <table><tr><td>None</td></tr><tr><td>Mild</td></tr><tr><td>Moderate</td></tr><tr><td>Severe</td></tr><tr><td>Very Severe</td></tr></table>	None	Mild	Moderate	Severe	Very Severe
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23-JUL-2018 | 01:38 PM

Daily Symptom Diary

Daily Symptom Diary

The next question asks you to record the number of times vomiting occurred in the last 24 hours. Please record the number of vomits (throwing up with food or liquid coming out) that occurred in the last 24 hours.

Record zero if you have not vomited during the past 24 hours. If you vomited, record the number of all vomits. If you vomited once, record one. If you vomited three times during the day, record three. If you vomited three times, whether it was during the same trip to the bathroom or three separate trips, record three as the number of episodes of vomiting.

Please record the number of vomits (throwing up with food or liquid coming out) that occurred in the last 24 hours.

5. During the past 24 hours, how many episodes of vomiting did you have?

1	2	3
4	5	6
7	8	9
×	0	.

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© YPrime 2018 23-JUL-2018 02:06 PM Daily Symptom Diary	© YPrime 2018 10-AUG-2018 11:39 AM Daily Symptom Diary									
<p>Please record the number of vomits (throwing up with food or liquid coming out) that occurred in the <u>last 24 hours</u>.</p> <p>5. During the past 24 hours, how many episodes of vomiting did you have?</p> <div><p>Info</p><p>You reported 0 vomiting episodes. Please confirm this is correct.</p><p>CANCEL CONFIRM</p><table><tr><td>4</td><td>5</td><td>6</td></tr><tr><td>7</td><td>8</td><td>9</td></tr><tr><td>×</td><td>0</td><td>•</td></tr></table></div>	4	5	6	7	8	9	×	0	•	<p>6. Thinking about your gastroparesis disorder, what was the overall severity of your gastroparesis symptoms today (<u>during the past 24 hours</u>)?</p> <div><p>None</p><p>Mild</p><p>Moderate</p><p>Severe</p><p>Very Severe</p></div>
4	5	6								
7	8	9								
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<p>< Back Next ></p>	<p>< Back Next ></p>									



© YPrime 2018 10-AUG-2018 01:17 PM Daily Symptom Diary	© YPrime 2017 16-JUN-2017 01:57 PM Daily Symptom Diary
<p>6. Thinking about your gastroparesis disorder, what was the overall severity of your gastroparesis symptoms today (<u>during the past 24 hours</u>)?</p> <p>None</p> <div><p>Warning</p><p>*Please be sure to answer all questions.</p><p>OK</p></div>	<p>You've completed this questionnaire. To review your answers select back. To finish select save. Once saved, responses cannot be changed.</p> <p>Save ✓</p>
<p>< Back Next ></p>	<p>< Back</p>



**Takeda TAK-906-2002
eCOA Screen Report, Version 1.0**

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Training

Training

Welcome to the Training Diary!

This training will allow you to practice and complete a set of questions that you need to answer every day after receiving your device. The practice data will not be saved.

Please complete all sections of this training to become familiar with this electronic diary and understand the order of expected daily records. Thank you for your time and participation.

Select "Next" to continue.

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Training

Training

Study Reminders:

The data entered in your diary daily after this training is very important for the completion of this study. Not completing your diary every day may prevent you from being part of this study.

To maintain accurate records, please complete the Morning and Evening entries as soon as possible to the actual time of taking the study medication and your meals.

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Training	Training
Training	Training
<p><u>Study Reminders:</u></p> <p>The Daily Symptom Diary must be completed at the end of each day, preferably before bedtime. It is recommended that this be completed after 8:00PM.</p> <p>Keep your device charging when not in use.</p> <p>Remember to bring your diary device with you to ALL study visits.</p>	<p>Instructions: The following questions ask about bloating severity you may have each day.</p> <p>Please complete the Bloating Severity Scale at about the same time every evening.</p> <p>For the bloating symptom, please <u>select the answer that best describes the worst severity of bloating during the past 24 hours</u>. Please be sure to answer each question.</p>
< Back Next >	< Back Next >



© YPrime 2018 23-JUL-2018 01:35 PM© YPrime 2018 24-JUL-2018 12:47 PM						
Training	Training					
Training	Training					
<p>Please select the answer that best describes the <u>worst severity</u> of this symptom <u>during the past 24 hours</u>.</p> <p>Bloating (feeling like you need to loosen your clothes)</p> <table border="1"><tbody><tr><td>None</td></tr><tr><td>Mild</td></tr><tr><td>Moderate</td></tr><tr><td>Severe</td></tr><tr><td>Very Severe</td></tr></tbody></table>	None	Mild	Moderate	Severe	Very Severe	<p>Instructions: The following questions ask about symptoms you may have each day.</p> <p>Please complete the daily diary at about the same time every evening.</p> <p>For each symptom, please <u>select the answer</u> that best describes the <u>worst severity</u> of each symptom <u>during the past 24 hours</u>. Please be sure to answer each question.</p>
None						
Mild						
Moderate						
Severe						
Very Severe						
< Back	< Back					
Next >	Next >					



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Training

Training

Please select the answer that best describes the worst severity of this symptom during the past 24 hours.

1. Nausea (feeling sick to your stomach as if you were going to vomit or throw up)

None

Mild

Moderate

Severe

Very Severe

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Training

Training

Please select the answer that best describes the worst severity of this symptom during the past 24 hours.

2. Not able to finish a normal-sized meal (for a healthy person)

None

Mild

Moderate

Severe

Very Severe

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Training	Training										
Training	Training										
<p>Please select the answer that best describes the <u>worst severity</u> of this symptom <u>during the past 24 hours</u>.</p> <p>3. Feeling excessively full after meals</p> <table border="1"><tr><td>None</td></tr><tr><td>Mild</td></tr><tr><td>Moderate</td></tr><tr><td>Severe</td></tr><tr><td>Very Severe</td></tr></table>	None	Mild	Moderate	Severe	Very Severe	<p>Please select the answer that best describes the <u>worst severity</u> of this symptom <u>during the past 24 hours</u>.</p> <p>4. Upper abdominal pain (above the navel)</p> <table border="1"><tr><td>None</td></tr><tr><td>Mild</td></tr><tr><td>Moderate</td></tr><tr><td>Severe</td></tr><tr><td>Very Severe</td></tr></table>	None	Mild	Moderate	Severe	Very Severe
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Very Severe											
< Back	Next >										



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eCOA Screen Report, Version 1.0

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Training

Training

The next question asks you to record the number of times vomiting occurred in the last 24 hours. Please record the number of vomits (throwing up with food or liquid coming out) that occurred in the last 24 hours.

Record zero if you have not vomited during the past 24 hours. If you vomited, record the number of all vomits. If you vomited once, record one. If you vomited three times during the day, record three. If you vomited three times, whether it was during the same trip to the bathroom or three separate trips, record three as the number of episodes of vomiting.

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Training

Training

Please record the number of vomits (throwing up with food or liquid coming out) that occurred in the last 24 hours.

5. During the past 24 hours, how many episodes of vomiting did you have?

1	2	3
4	5	6
7	8	9
×	0	.

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Training

Training

6. Thinking about your gastroparesis disorder, what was the overall severity of your gastroparesis symptoms today (during the past 24 hours)?

None

Mild

Moderate

Severe

Very Severe

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Training

Training

You have completed this entry.

To review your answers, select "Back".

To finish, select "Save".

Once saved, responses cannot be changed.

Save ✓

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Subject Assignment

Please select a subject

100124	👤
100123	👤
100121	👤
100122	👤
1001211	👤
100126	👤
1001210	👤
1001212	👤
1001207	👤

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You missed YESTERDAY'S entries.


You must complete YESTERDAY'S entries even if you did not take your dose or eat a meal YESTERDAY.

The following screens are for YESTERDAY'S scheduled entries.

COMPLETE DIARY NOW

[← Back](#)

**Morning Entry Reminder** 17:32
Please complete your Morning Entries

**Evening Entry Reminder** 17:32
Please complete your Evening Entries