

Patient-Reported IBS-C Symptom Severity Correlates Positively With Financial Burden: IBS In America 2024 Real-World Survey

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Background

- Irritable bowel syndrome with constipation (IBS-C) is known to impose a significant financial burden on patients in terms of direct and indirect healthcare costs.^{1,2}
- The IBS In America 2024 online survey was designed to gain insight into the experiences of individuals with IBS nationwide, including health status, quality of life, and symptom burden.^{3,4}
- This study was carried out using real-world data from the IBS In America 2024 survey to characterize the relationship between participant-reported IBS-C symptom severity and financial toxicity.

Methods

Study Design

- Ardelyx supported the IBS In America 2024 survey extension study in partnership with Health Union from January 15 to April 14, 2024.
- Participants were United States (US) residents aged ≥18 years who met these self-reported criteria: had been diagnosed with IBS-C, were currently seeing a health care provider to treat IBS-C, and had used over-the-counter or prescription treatment for IBS-C.
- Financial toxicity was assessed using select items from the Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity (FACT-COST®) scale, Version 2.⁵
 - The full scale includes 12 statements with responses ranging from "Not at all" to "Very much," as applicable within the past 7 days.
- In this analysis, an overall FACIT-COST score was not calculated because the full FACIT-COST assessment was not used, and the outcomes were not interpreted in the context of other research using the FACIT-COST assessment.
- Symptoms of IBS-C were assessed using 2 Patient-Reported Outcomes Measurement Information System® (PROMIS®) gastrointestinal (GI) symptom scales.^{6,7}
 - The PROMIS Scale v1.0 -- Gastrointestinal Belly Pain 5a (PROMIS GI Belly Pain) scale includes 5 items that assess abdominal pain frequency, intensity, and quality over the past 7 days, as well as bothersomeness and interference with daily activities.
 - The PROMIS Scale v1.0 -- Gastrointestinal Constipation 9a (PROMIS GI Constipation) scale includes 9 items that assess constipation-related symptoms and the bothersomeness of these symptoms over the past 7 days.
- Both PROMIS GI measures use T-scores. A higher T-score represents more of the concept being measured.⁸
 - A score of 50 represents the average of the US general population, while T-scores of 60 and 40 are 1 standard deviation worse and better than average, respectively.

Statistical Methods

- Financial burden was rated as a function of the following:
 - PROMIS GI Scale scores (T-score <60 vs ≥60).
 - Well controlled on current IBS treatment plan (not vs somewhat vs very well controlled).
 - Frequency of IBS-C episodes (daily vs weekly or less often).
- Pearson correlations were used to assess covariation between financial toxicity and symptom severity items.
- One-way analysis of variance (ANOVA) and multivariate analysis of variance (MANOVA) analyses were used to assess differences in financial toxicity between levels of symptom severity.

Results

Respondents (Table 1)

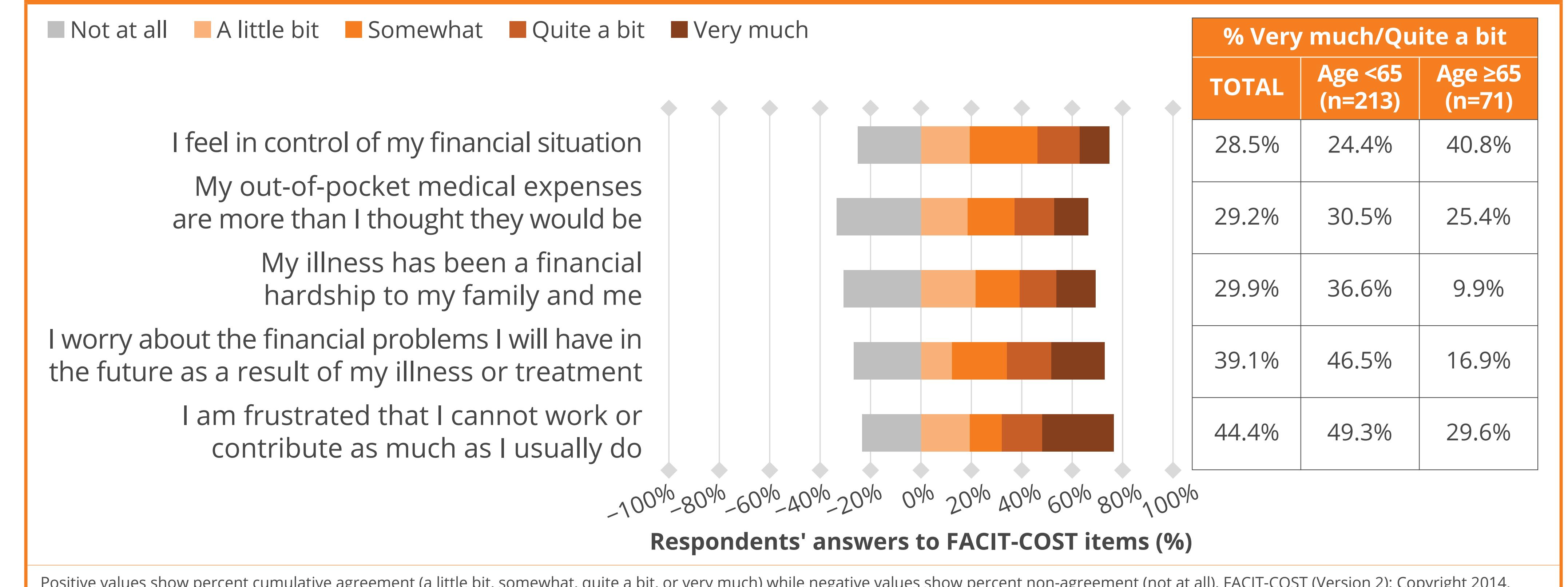
- Respondents were predominantly female (92%) and White (87%).
- Health-Related Economic Burden (Figure 1)**
- Agreement with financial toxicity items differed significantly by age:
 - Significantly fewer respondents aged <65 years felt in control of their financial situation compared with those aged ≥65 years ($F(1,282)=7.181$; $P<0.01$).
 - Significantly more respondents aged <65 years reported greater financial hardship ($F(1,282)=19.290$; $P<0.001$), concerns about their financial future ($F(1,282)=20.886$; $P<0.001$), and frustrations about work or contributions ($F(1,282)=8.583$; $P<0.005$) versus those aged ≥65 years.

Table 1: Respondent Demographics and Disease Characteristics

| | IBS-C respondents (N=284) | |
|---|--------------------------------|-----------|
| Age, mean (SD), y | 51.4 (15.5) | |
| Gender, ^a n (%) | Female | 261 (92) |
| | Male | 21 (7) |
| | Non-binary | 2 (1) |
| Race/ethnicity, n (%) | White or Caucasian | 246 (87) |
| | Black or African-American | 28 (10) |
| | Hispanic or Latino | 12 (4) |
| | Other ^b | 15 (5) |
| IBS-C diagnosed by HCP, n (%) | Yes | 284 (100) |
| | No | 0 (0) |
| Time since diagnosis, n (%) | 0-5 years ago | 94 (33) |
| | >5-15 years ago | 103 (36) |
| | ≥15 years ago | 87 (31) |
| Frequency of IBS episodes over past year, n (%) | Daily | 102 (36) |
| | Weekly | 125 (44) |
| | Monthly | 39 (14) |
| | Every few months or less often | 18 (6) |

^aSelf-identified gender. ^bNative American or Alaska Native, Asian or South Asian, Middle Eastern or North African, Native Hawaiian or Other Pacific Islander, Other race or ethnicity, or Prefer not to answer. HCP, health care provider; IBS, irritable bowel syndrome; IBS-C, irritable bowel syndrome with constipation.

Figure 1: FACIT-COST: Health-Related Economic Burden



Positive values show percent cumulative agreement (a little bit, somewhat, quite a bit, or very much) while negative values show percent non-agreement (not at all). FACIT-COST (Version 2): Copyright 2014, FACIT-The University of Chicago, Used with permission. FACIT-COST, Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity.

Symptom Severity

- The mean T-scores were 60.8 and 62.3 for the PROMIS GI Constipation Scale and PROMIS GI Belly Pain Scale, respectively.

Relationships Between Financial Toxicity and Symptom Severity/Control

- Responses on the FACIT measures of financial toxicity correlated positively with the severity of constipation, abdominal pain, and IBS episode frequency, and correlated negatively with reported control of IBS on the current treatment plan (Table 2).
- Overall financial toxicity was significantly related to constipation severity, abdominal pain severity, the level of IBS control on the current treatment plan, and IBS episode frequency (Table 3).
- Participants with higher PROMIS Scale T-scores for constipation (Figure 2A) and abdominal pain (Figure 2B) reported greater financial burden across all financial toxicity items versus participants with lower T-scores.
- Poor IBS symptom control and higher frequency of IBS episodes had a significant negative impact on participants' financial situation (Figure 3A and 3B).

Table 2: Relationships Between Financial Toxicity Items and Symptom Severity: Results From Pearson Correlations

| FACIT-COST item | PROMIS GI Constipation Scale T-score | PROMIS GI Belly Pain T-score | My IBS is well controlled with my current treatment plan ^a | Frequency of IBS-C episodes ^b |
|---|--------------------------------------|------------------------------|---|--|
| I am frustrated that I cannot work or contribute as much as I usually do | 0.282 ^c | 0.442 ^c | -0.330 ^d | 0.171 ^c |
| I worry about the financial problems I will have in the future as a result of my illness or treatment | 0.339 ^c | 0.456 ^c | -0.277 ^d | 0.177 ^c |
| My illness has been a financial hardship to my family and me | 0.307 ^c | 0.407 ^c | -0.279 ^d | 0.143 ^c |
| My out-of-pocket medical expenses are more than I thought they would be | 0.268 ^c | 0.332 ^c | -0.199 ^d | 0.113 ^e |
| I feel in control of my financial situation | -0.200 ^d | -0.141 ^d | 0.178 ^c | 0.006 ^e |

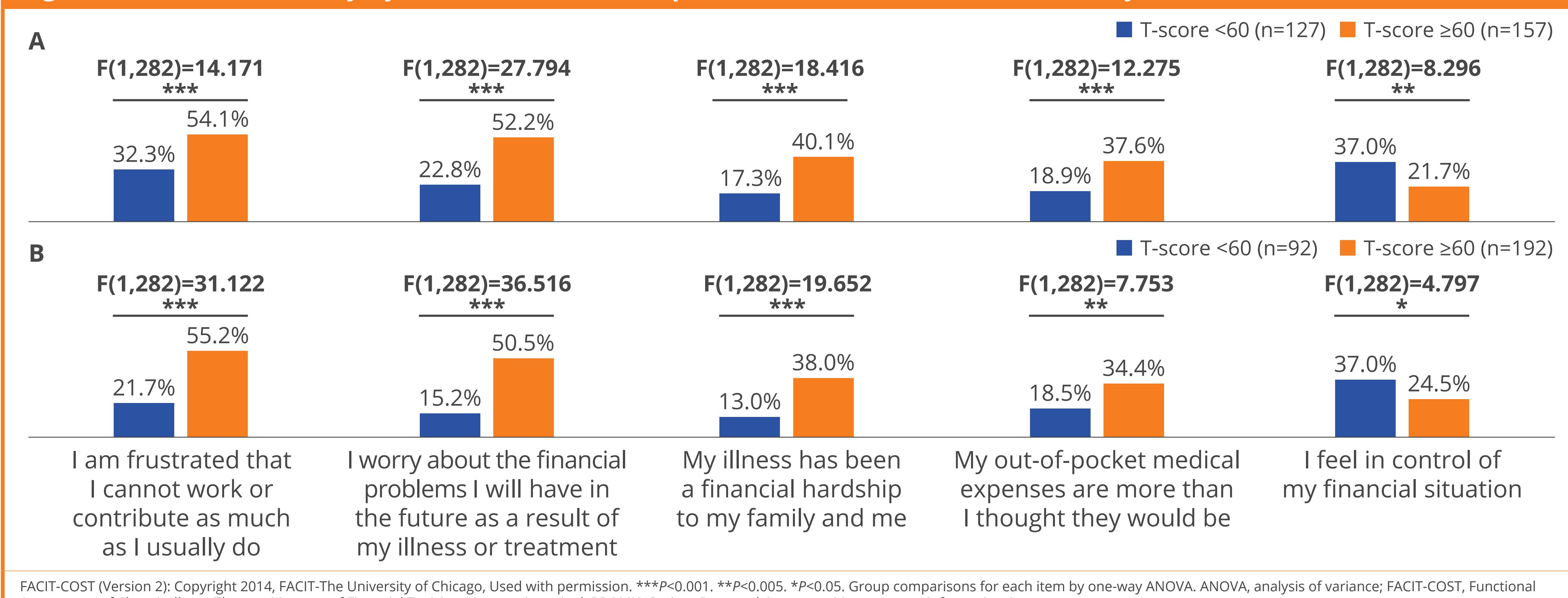
FACIT-COST (Version 2): Copyright 2014, FACIT-The University of Chicago, Used with permission. ^aIBS symptom control assessed by level of agreement or disagreement with this statement. ^bIBS episode frequency assessed by response to, "Within the past year, how frequently have you experienced IBS episodes?" Participants could select Daily, Weekly, Monthly, or Every few months or less often. ^cSignificant positive correlation. ^dSignificant negative correlation. ^eNot significant. FACIT-COST, Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity; GI, gastrointestinal; IBS, irritable bowel syndrome; IBS-C, irritable bowel syndrome with constipation; PROMIS, Patient-Reported Outcomes Measurement Information System.

Table 3: Overall Financial Toxicity by Each IBS Symptom Severity Item: Results From Multivariate Analyses

| | PROMIS GI Constipation Scale T-score | PROMIS GI Belly Pain Scale T-score | My IBS is well controlled with my current treatment plan | Frequency of IBS-C episodes |
|------------------|---|---|---|---|
| FACIT-COST items | Pillai's Trace=0.114 F=7.1685 df=(5,278); P<0.001 | Pillai's Trace=0.167 F=11.155 df=(5,278); P<0.001 | Pillai's Trace=0.101 F=6.2716 df=(5,278); P<0.001 | Pillai's Trace=0.0472 F=2.7532 df=(5,278); P<0.05 |

For the FACIT-COST items, the top 3 responses (somewhat, quite a bit, or very much) were used for the multivariate model except for the statement "I feel in control of my financial situation," for which the bottom 3 responses (not at all, a little bit, or somewhat) were used. FACIT-COST, Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity; GI, gastrointestinal; IBS, irritable bowel syndrome; IBS-C, irritable bowel syndrome with constipation; PROMIS, Patient-Reported Outcomes Measurement Information System.

Figure 2: Financial Toxicity by (A) PROMIS GI Constipation Scale and (B) PROMIS GI Belly Pain Scale T-Scores



FACIT-COST (Version 2): Copyright 2014, FACIT-The University of Chicago, Used with permission. ***P<0.001, **P<0.005, *P<0.05. Group comparisons for each item by one-way ANOVA. ANOVA, analysis of variance; FACIT-COST, Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity; GI, gastrointestinal; IBS, irritable bowel syndrome; ns, not significant.

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FACIT-COST (Version 2): Copyright 2014, FACIT-The University of Chicago, Used with permission. ***P<0

IBSREL[®] (tenapanor) is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults

Important Safety Information

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

- IBSREL[®] is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile rats, administration of tenapanor caused deaths presumed to be due to dehydration. [see *PI Contraindications (4), Use in Specific Populations (8.4)*].
- Avoid use of IBSREL[®] in patients 6 years to less than 12 years of age. [see *PI Warnings and Precautions (5.1), Use in Specific Populations (8.4)*].
- The safety and effectiveness of IBSREL[®] have not been established in pediatric patients less than 18 years of age. [see *PI Use in Specific Populations (8.4)*].

CONTRAINDICATIONS

IBSREL[®] is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.

IBSREL[®] is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

WARNINGS AND PRECAUTIONS

Risk of Serious Dehydration in Pediatric Patients

IBSREL[®] is contraindicated in patients below 6 years of age. The safety and effectiveness of IBSREL[®] in patients less than 18 years of age have not been established. In young juvenile rats (less than 1 week old; approximate human age equivalent of less than 2 years of age), decreased body weight and deaths occurred, presumed to be due to dehydration, following oral administration of tenapanor. There are no data available in older juvenile rats (human age equivalent 2 years to less than 12 years).

Avoid the use of IBSREL[®] in patients 6 years to less than 12 years of age. Although there are no data in older juvenile rats, given the deaths in younger rats and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of IBSREL[®] in patients 6 years to less than 12 years of age.

Diarrhea

Diarrhea was the most common adverse reaction in two randomized, double-blind, placebo-controlled trials of IBS-C. Severe diarrhea was reported in 2.5% of IBSREL[®]-treated patients. If severe diarrhea occurs, suspend dosing and rehydrate patient.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions in IBSREL[®]-treated patients (incidence $\geq 2\%$ and greater than placebo) were: diarrhea (16% vs 4% placebo), abdominal distension (3% vs <1%), flatulence (3% vs 1%) and dizziness (2% vs <1%).

For additional safety information, including the Boxed Warning, please see full Prescribing Information: [click here](#).

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IBS-C, irritable bowel syndrome with constipation.

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