

Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: Physician Surveys on Experiences with REMS Programs

OMB Control Number: 0910-0847

Expiration Date: 12/31/2022



Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0847. The time required to complete this portion of the information collection is estimated to average 2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASStaff@fda.hhs.gov.

National Survey of Physician Experiences with Bosentan

Thank you for agreeing to participate in this survey relating to your experiences prescribing bosentan. This research is being conducted by investigators at Brigham and Women's Hospital / Harvard Medical School on behalf of the US Food and Drug Administration (FDA). If you have NOT prescribed bosentan in the last year, **please email Sandra Applebaum, MS (sandra.applebaum@luminasllc.com) at Luminas, the survey administrator, and DO NOT proceed further.**

Your participation in the survey is voluntary, and you may withdraw at any time. Your responses will be aggregated with other responses and analyzed in a de-identified manner. The survey methods have been approved by the Institutional Review Board at Brigham and Women's Hospital and the FDA Research Involving Human Subjects Committee.

The survey should take approximately 20 minutes to complete. In addition to the \$20 enclosed in this packet, following completion, you will be asked for your email address and emailed a \$80 Amazon gift card as a token of appreciation. This survey is not connected in any way with a pharmaceutical manufacturer.

We appreciate your contribution to this important topic. Thank you in advance for your participation!

Instructions for Completing the Survey

- **As a reminder, you can take the survey online if you prefer at the following link: [link].**
- Using a blue or black pen, place an "X" in the box next to the appropriate response as shown: .
- If asked to provide a written response to a question, please PRINT legibly in the space provided.
- If completing the paper questionnaire, please return it in the enclosed postage-paid envelope.

Section A: Prescribing and Certification Requirements

We will start the survey by getting a better understanding of your experience with bosentan.

A1. Approximately when was the last time you prescribed bosentan?

month year

A2. Approximately how many of your patients have you prescribed bosentan to over the last 3 years?

₁ 1-10 patients
₂ 11-20 patients
₃ 21 or more patients

A3. Approximately how many women of reproductive potential have you prescribed bosentan to over the last 3 years?

₁ 1-5 patients
₂ 6-10 patients
₃ 11 or more patients

Before prescribing bosentan, physicians must go through a certification process administered by the manufacturer. The certification process typically involves such activities as reviewing certain materials, training, and filling out forms.

A4. Approximately how many years ago did you first complete the certification process for bosentan?

years ago

A5. How well do you recall the certification process that allowed you to begin to prescribe bosentan?

₁ Very well
₂ Moderately well
₃ Slightly well
₄ Not well at all

A6. Did the certification process for bosentan provide information on the following risks?

	Yes	No	I don't remember
a. Birth defects (women of reproductive potential)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
b. Decreased hemoglobin count	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
c. Liver damage	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
d. Pulmonary edema	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
e. Respiratory infections	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
f. Stroke	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃

A7. When you start a patient on bosentan, how often do you discuss the following risks?

	Never (0% of the time)	Rarely (1%-5% of the time)	Sometimes (6%-25% of the time)	Often (26%-50% of the time)	Most of the time (51%-75% of the time)	Always/almost always (76% of the time or more)
a. Birth defects (women of reproductive potential)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
b. Decreased hemoglobin count	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
c. Liver damage	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
d. Pulmonary edema	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
e. Respiratory infections	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
f. Stroke	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆

A8. Using a scale from 1 (most) to 4 (least), please rank the following risks to patients receiving bosentan in order of their magnitude of concern to you.

- 1 Birth defects (women of reproductive potential)
- 2 Decreased sperm count (men)
- 3 Decreased hemoglobin count
- 4 Pulmonary edema

A9. Using a scale from 1 (most) to 5 (least), please rank the usefulness of the following sources of information in contributing to your understanding of the risks of bosentan.

- 1 Clinical decision support tools (e.g., UpToDate, MicroMedex, ePocrates)
- 2 Manufacturer sales representatives' presentations or materials
- 3 Professional colleagues
- 4 Studies and other articles published in medical journals
- 5 The drug's FDA-approved labeling

**A10. At first, how frequently must the testing required for bosentan be performed?
If fewer than 10 weeks, please enter as 2 digits, e.g., 04.**

Every weeks

A11. Please indicate to what extent you agree or disagree with the following statements.

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
a. It is reasonable that bosentan has a certification process, while other drugs I prescribe for my patients with pulmonary arterial hypertension do not have a certification process.	<input type="text"/> _1	<input type="text"/> _2	<input type="text"/> _3	<input type="text"/> _4	<input type="text"/> _5
b. The certification process provided me with useful information about bosentan.	<input type="text"/> _1	<input type="text"/> _2	<input type="text"/> _3	<input type="text"/> _4	<input type="text"/> _5
c. The certification process for bosentan took too long to complete.	<input type="text"/> _1	<input type="text"/> _2	<input type="text"/> _3	<input type="text"/> _4	<input type="text"/> _5
d. The educational materials provided as part of the certification process should include information about any clinically important risk of bosentan.	<input type="text"/> _1	<input type="text"/> _2	<input type="text"/> _3	<input type="text"/> _4	<input type="text"/> _5
e. The educational materials provided as part of the certification process should include information about how well bosentan is expected to work.	<input type="text"/> _1	<input type="text"/> _2	<input type="text"/> _3	<input type="text"/> _4	<input type="text"/> _5
f. The certification process effectively explained the testing required of patients receiving bosentan.	<input type="text"/> _1	<input type="text"/> _2	<input type="text"/> _3	<input type="text"/> _4	<input type="text"/> _5
g. Prescribers should be required to pass a quiz covering drug risks and testing requirements to complete the bosentan certification process.	<input type="text"/> _1	<input type="text"/> _2	<input type="text"/> _3	<input type="text"/> _4	<input type="text"/> _5
h. Physicians should be required to repeat the certification process each year while they are active prescribers of bosentan.	<input type="text"/> _1	<input type="text"/> _2	<input type="text"/> _3	<input type="text"/> _4	<input type="text"/> _5
i. Physicians should be compensated for having to complete the certification process for bosentan.	<input type="text"/> _1	<input type="text"/> _2	<input type="text"/> _3	<input type="text"/> _4	<input type="text"/> _5

Section B: Patient Initiation and Monitoring

As you may know, prior to and while taking bosentan, patients are also required to follow certain “safe use requirements”.

B1. To receive an initial prescription for bosentan, patients must do the following:

	Yes	No	Not sure
a. Get a liver function test	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
b. Get a pregnancy test (women of reproductive potential)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
c. Get a urinalysis	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
d. Use at least one form of contraception (women of reproductive potential)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃

B2. When you prescribe bosentan, how long, on average, do you or someone on your team spend explaining to patients the safe use requirements related to the drug?

- ₁ We do not discuss safe use requirements with my patients.
- ₂ 5 minutes or less
- ₃ 6-10 minutes
- ₄ 11-15 minutes
- ₅ More than 15 minutes

B3. Who on your clinical team is primarily responsible for helping patients complete administrative paperwork or enrollment forms involved with the safe use requirements?

- ₁ I am
- ₂ A nurse practitioner or registered nurse
- ₃ A physician assistant
- ₄ Other (Please specify: _____)
- ₅ No one

B4. Do your patients receive from you or your team any other materials describing the risks of taking bosentan?

- ₁ Yes
- ₂ No → **GO TO B6.**

B5. What materials do you or your team provide describing the risks or harms of bosentan? Please check all that apply.

- ₁ Published articles or stories
- ₂ Links to manufacturer website
- ₃ Links to any non-manufacturer websites
- ₄ Pamphlets or brochures produced by the manufacturer
- ₅ Pamphlets or brochures produced by you or your institution
- ₆ Other materials (Please specify: _____)

B6. After learning about the safe use requirements for bosentan, how often do your patients seek another treatment option instead?

- ₁ Never (0% of the time)
- ₂ Rarely (1%-5% of the time)
- ₃ Sometimes (6%-25% of the time)
- ₄ Often (26%-50% of the time)

- ₅ Most of the time (51%-75% of the time)
- ₆ Always/almost always (76% of the time or more)

B7. In your estimation, how frequently do your patients follow the testing schedule that is part of the safe use requirements?

- ₁ Never (0% of the time)
- ₂ Rarely (1%-5% of the time)
- ₃ Sometimes (6%-25% of the time)
- ₄ Often (26%-50% of the time)
- ₅ Most of the time (51%-75% of the time)
- ₆ Always/almost always (76% of the time or more)

B8. Please indicate to what extent you agree or disagree with the following statements.

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
a. The testing requirement is clinically necessary for safe use of bosentan.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
b. The paperwork involved with the safe use requirements facilitates discussion about bosentan between patients and me or my team.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
c. The safe use requirements are burdensome for most patients.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
d. The safe use requirements have often caused a delay in my patients receiving their medication.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
e. Insurance issues have often caused a delay in my patients receiving their medication.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
f. Insurance issues are more burdensome than safe use requirements for most patients.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Section C: Overall Experiences and Perceptions and Reforms

C1. Please rate how easy or hard it is to complete the following tasks related to prescribing bosentan.

	Very easy	Somewhat easy	Neither easy nor hard	Somewhat hard	Very hard
a. The physician certification process	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
b. The patient enrollment process	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
c. Testing patients	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
d. Reporting testing findings	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

C2. How willing would you be to prescribe bosentan if it were not subject to...?

	Very willing	Somewhat willing	Neither willing nor unwilling	Somewhat unwilling	Very unwilling
a. Physician certification requirements	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
b. Patient safe use requirements	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

C3. How often are patients needing bosentan referred to you by other physicians in your specialty because they are not certified to prescribe it?

- ₁ A lot
- ₂ Sometimes
- ₃ Never

Please indicate to what extent you agree or disagree with the following statements:

C4. Overall, the positives of the ...

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
a. Prescriber certification process for bosentan outweigh the negatives.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
b. Patient safe use requirements for bosentan outweigh the negatives.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

C5. What feedback would you give FDA or the manufacturer on the physician certification process for bosentan? Please print clearly in the box below. If you need more space, continue on the back cover. Be sure to include the question number.

C6. What feedback would you give FDA or the manufacturer on the patient safe use requirements for bosentan? Please print clearly in the box below. If you need more space, continue on the back cover. Be sure to include the question number.

Section D: Demographics

D1. What gender do you identify as...?

Mark only one oval:

- ₁ Male
- ₂ Female
- ₃ Prefer not to answer

D2. Which of the following best describes your race? Mark one or more.

- ₁ American Indian or Alaska Native
- ₂ Asian
- ₃ Black or African-American
- ₄ Native Hawaiian or Other Pacific Islander
- ₅ White
- ₆ Prefer not to answer

D3. Are you of Hispanic, Latino, or Spanish origin?

- ₁ Yes
- ₂ No

D4. What year did you graduate from medical school?

D5. Which of the following best describes your specialty? You may select up to 2.

- | | |
|---|--|
| <input type="checkbox"/> ₁ Allergy/Immunology | <input type="checkbox"/> ₁₆ Ophthalmology |
| <input type="checkbox"/> ₂ Anesthesiology | <input type="checkbox"/> ₁₇ Orthopedics |
| <input type="checkbox"/> ₃ Cardiology | <input type="checkbox"/> ₁₈ Otolaryngology |
| <input type="checkbox"/> ₄ Dermatology | <input type="checkbox"/> ₁₉ Pathology |
| <input type="checkbox"/> ₅ Endocrinology | <input type="checkbox"/> ₂₀ Pediatrics |
| <input type="checkbox"/> ₆ Emergency Medicine | <input type="checkbox"/> ₂₁ Physical Medicine and Rehab |
| <input type="checkbox"/> ₇ Family/General Practice | <input type="checkbox"/> ₂₂ Plastic Surgery |
| <input type="checkbox"/> ₈ Geriatrics | <input type="checkbox"/> ₂₃ Preventive Medicine |
| <input type="checkbox"/> ₉ Internal Medicine | <input type="checkbox"/> ₂₄ Psychology |
| <input type="checkbox"/> ₁₀ Medical Genetics | <input type="checkbox"/> ₂₅ Pulmonology |
| <input type="checkbox"/> ₁₁ Neurological Surgery | <input type="checkbox"/> ₂₆ Radiology |
| <input type="checkbox"/> ₁₂ Nephrology | <input type="checkbox"/> ₂₇ Rheumatology |
| <input type="checkbox"/> ₁₃ Neurology | <input type="checkbox"/> ₂₈ Sleep medicine |
| <input type="checkbox"/> ₁₄ Obstetrics/Gynecology | <input type="checkbox"/> ₂₉ Surgery |
| <input type="checkbox"/> ₁₅ Oncology | <input type="checkbox"/> ₃₀ Urology |

₃₁ Other (Please specify: _____)

D6. In what ZIP code is your practice located?

D7. In what clinical settings do you prescribe bosentan? You may select more than one.

- ₁ Outpatient clinic (solo practice)
- ₂ Outpatient clinic (group practice)
- ₃ Community hospital (non-military/VA)
- ₄ Academic hospital (non-military/VA)
- ₅ Military or VA hospital
- ₆ Other (Please specify: _____)

D8. What percentage of your professional time is spent in direct patient care?

percent

D9. Have you received any of the following from Actelion, the brand-name manufacturer of bosentan, over the past three years? Please select all that apply.

- ₁ Speaker fees
- ₂ Payment for membership on an advisory board
- ₃ Research grants
- ₄ Other benefits (Please specify: _____)

D10. Please provide your email address to receive your gift card: _____

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY. PLEASE RETURN YOUR COMPLETED QUESTIONNAIRE IN THE ENCLOSED ENVELOPE OR MAIL IT TO:

*Adapt, Inc.
Physician Survey
5610 Rowland Road
Suite 160
Minnetonka, MN 55343*