

TERMS OF USE

Last Updated: March 13, 2023

Please read these Terms of Use (the “[Agreement](#)”) carefully. By using the Service (as defined below), you agree to this Agreement. We recommend that you print a copy of this Agreement for future reference. This Agreement may be updated from time to time.

This Agreement is between you and the Macitentan REMS (Risk Evaluation and Mitigation Strategy), (“[we](#)” or “[us](#)” or “[our](#)”), a consortium of manufacturers, its agents, affiliates, and authorized representatives, concerning your use of the website located at www.MacitentanREMS.com (the “[Site](#)” or “[Service](#)”) in connection with the Macitentan REMS. We are the governing body of the Macitentan REMS. The Macitentan REMS is required and regulated by the U.S. Food and Drug Administration (FDA).

If you are not willing to accept the terms and conditions in the Agreement, we ask that you not access or use the Service or post or submit any materials on the Site. Please review our Privacy Policy located at [Privacy Policy](#) for details about what information is collected and how it is used.

This Site is intended for and directed to residents of the United States and its territories. You affirm that you are of legal age to enter into this Agreement. This Site is not intended for use by persons under the age of 18. If you are under 18 years old, you may not use this Site or provide any Personal Information.

If you are using the Service on behalf of, or for the benefit of, any organization with which you are associated, then you agree to the terms of this Agreement on behalf of yourself and such organization, and you confirm that you have the legal authority to bind such organization to this Agreement. References to “you” and “your” in this Agreement will refer to both you and any such organization.

1. Our Right to Make Changes. We may change this Agreement from time to time (for any reason, such as changes in the functions or services offered by this Site or to reflect a change in the law) by notifying you of such changes by any reasonable means and by making available a revised Agreement through the Service. The “*Last Updated*” date above indicates when this Agreement was last changed.

To the extent permitted or required by applicable law and regulations, we may, at any time and without liability, modify or discontinue all or part of the Service (e.g., to comply with relevant laws and regulations, to protect the security of the Service or to implement reasonable technical adjustments and improvements, to modify the services and functions provided by the Site). We will seek to notify you by reasonable means of any modifications that will affect your use of the Service, taken as a whole.

2. Information Disclaimer. The information, including any advice and recommendations provided as part of the Service is intended solely for educational and informational purposes and to comply with the requirements of the Macitentan REMS. It is not intended as medical or healthcare advice, or to be used for medical diagnosis or treatment for any individual problem. It is also not intended as a substitute for professional advice and services from a qualified healthcare provider familiar with your unique facts. Always seek the advice of your doctor or other qualified healthcare provider regarding any medical condition and before starting any new treatment within the Macitentan REMS. Your use of the Service is subject to the additional disclaimers and caveats that may appear throughout the Service.

We assume no responsibility for any consequence relating directly or indirectly to any action or inaction you take based on the information, or other material provided as part of the Service. While we strive to keep the information provided by the Service to be accurate, complete, and up-to-date, we do not give any assurances, and will not be responsible for, any damage or loss related to the accuracy, completeness, or timeliness of the information provided as part of the Service.

3. Information Submitted Through the Service. Your submission of information through the Service is governed by our Privacy Policy, located at [Privacy Policy](#).

4. Jurisdictional Issues. The Service may not be appropriate or available for use in some jurisdictions. Any use of the Service is at your own risk, and you must comply with all applicable laws, rules and regulations in doing so. The Services and Site are designed for and intended for users in the United States. We make no representation that the Site or Services are applicable to, appropriate for, or available to users in locations outside the United States. Accessing the Site and Services from territories where content contained on the Macitentan REMS is illegal, is prohibited. If you choose to access the Site and Services from a location outside the U.S., you do so on your own initiative and you are responsible for compliance with local laws.

5. Acceptable Use and Rules of Conduct. You must not:

- Post, transmit or otherwise make available through or in connection with the Service any materials that are or may be: (a) threatening, harassing, degrading, hateful, intimidating, or otherwise fail to respect the rights and dignity of others; (b) defamatory, libelous or fraudulent; (c) obscene, indecent, pornographic or otherwise objectionable; or (d) protected by copyright, trademark, trade secret, right of publicity or privacy or any other proprietary right, without the express prior written consent of the applicable owner.
- Post, transmit or otherwise make available through or in connection with the Service any virus, worm, Trojan horse, Easter egg, time bomb, spyware or other computer code, file or program that is or is potentially harmful or invasive or intended to damage or hijack the operation of, or to monitor the use of, any hardware, software or equipment (each, a “Virus”).
- Use the Service for any commercial purpose, including use for your commercial purposes or any commercial purposes that will benefit you in any way.
- Use the Service for any purpose that is fraudulent or otherwise unlawful.
- Collect information about users of the Service in any way, including through reverse engineering.
- Interfere with the operation of the Service or the servers or networks used to make the Service available, including by hacking or defacing any portion of the Service, or violate any requirement or policy of such servers or networks.
- Restrict or inhibit any other person from using the Service.
- Reproduce, modify, adapt, translate, create derivative works of, sell, rent, lease, loan, timeshare, distribute or otherwise exploit any portion of (or any use of) the Service except as expressly authorized under this Agreement, without our express prior written consent.
- Reverse engineer, decompile or disassemble any portion of the Service, except where such restriction is expressly prohibited by applicable law.
- Remove any copyright, trademark or other proprietary rights notice from the Service.
- Incorporate any portion of the Service into any product or service, without our express prior written consent.
- Systematically download and store Service content.
- Use any robot, spider, site search/retrieval application or other manual or automatic device to retrieve, index, “scrape,” “data mine” or otherwise gather Service content or reproduce or circumvent the navigational structure or presentation of the Service, without our express prior written consent. Notwithstanding the foregoing, and subject to compliance with any instructions posted in the robots.txt file located in the root directory of the Service, we grant to the operators of public search engines permission to use spiders to copy materials from the Service for the sole purpose of (and solely to the extent necessary for) creating publicly available, searchable indices of such materials, but not caches or archives of such materials. We reserve the right to revoke such permission either generally or in specific cases, at any time and without notice.

You are responsible for obtaining, maintaining and paying for all hardware, telecommunications and other services needed for you to use the Service. We may terminate immediately your access to the Site and take other legal action if you violate the above provisions.

6. Electronic Communications. The information communicated as part of the Service may constitute an electronic communication. When you communicate with us through the Service or via other forms of electronic media, such as e-mail, you are communicating with us electronically. You agree that we may communicate electronically, subject to local privacy and Anti-Spam laws, and that such communications, as well as notices, disclosures, agreements and other communications that we provide to you electronically, are equivalent to communications in writing and shall have the same force and effect as if they were in writing and signed by the party sending the communication.

In order to receive communications electronically, you must have a personal computer with a modem connected to a communications source (telephone, wireless or broadband), and a modern computer operating system that supports internet browsing via an HTTP/s connection such as Internet Explorer, Firefox, or Opera. You will need a printer attached to your personal computer to print any communications. All contracts completed electronically will be deemed for all legal purposes to be in writing and legally enforceable as a signed writing.

7. Registration. You may need to register and/or enroll to use the Service. We may reject, or require that you change, any username, password or other information that you provide. Your username and password are for your personal use only. You are solely responsible for maintaining the confidentiality of your credentials and for restricting access to your mobile device, computer and/or other means of accessing the Service. We are not responsible for any use of your credentials caused by your failure to keep them confidential. You are solely responsible for all activities that occur under your account, either with or without your knowledge. You must promptly notify us of any unauthorized use of your credentials or account of which you become aware. We recommend that, to the extent you access the Service via a mobile device, you password protect said device.

You agree that any information you provide to us will be current, accurate and complete and that you will keep such information up to date by notifying us of any changes.

We reserve the right to terminate any account at any time in our sole discretion and in accordance with Macitentan REMS requirements, including without limitation for any failure to comply with the Macitentan REMS requirements or these Terms of Use, any fraud or abuse, or any misrepresentation that you or anyone using your account may make to us.

8. Profiles and Forums. You may be permitted to make available certain information or materials (each, a “Submission”) in connection with the Service, including on profile pages or interactive features. We have no control over and are not responsible for any Submissions, any use or misuse by any third party of Submissions or for your interactions with other users. Users are ultimately responsible for their own actions. If you choose to make your personal or other information publicly available through the Service, you do so at your own risk.

You acknowledge that any forums contain the opinions and views of other users. You acknowledge further that we are not responsible for the accuracy of any Submissions on the Site. You understand and agree that all Submissions are the sole responsibility of the person who posted the Submission. You understand and agree that you will evaluate, and bear all risks associated with, the use of any Submission, including any reliance on the accuracy, completeness or usefulness of such Submission.

9. Monitoring Use of the Service. The Macitentan REMS may (but have no obligation to) monitor, evaluate, alter or remove Submissions before or after they appear on the Service or analyze your access to or use of the Service. The Macitentan REMS may disclose information regarding your access to and use of the Service, the circumstances surrounding the transmission of Submissions, and Personal Information regarding users who make Submissions available, in each case in accordance with applicable law or a request by a court or law enforcement or other governmental authority, or otherwise in accordance with our Privacy Policy.

10. Your Right to Use the Service. You acknowledge that all intellectual property rights in the Service, belong to us or our licensors. You have no right in or to the Service other than the right to access them in accordance with this Agreement. Subject to your compliance with, and solely for the duration of, this Agreement: you may view one copy of the Site on any single device, solely for your personal, non-commercial use. If you fail to comply with this Agreement or the requirements of the Macitentan REMS, you cease using the Service. You are responsible for keeping your device secure and protecting it appropriately.

11. Proprietary Rights. The Service is protected by proprietary rights and laws, applicable to brand names, Macitentan REMS Materials (i.e., all of the materials displayed on this website, including (without limitation) all information, text, graphics, names, design, software, documents), layout, copyrights, trademarks and service marks, and any associated logos. All trade names, copyrights, trademarks, service marks and logos (collectively, “Marks”) on the Service not owned by us are the property of their respective owners. You may not use our Marks in connection with any product or service that is not ours or in any manner that is likely to cause confusion. Nothing contained on the Service should be construed as granting any right to use any Marks without the express prior written consent of the owner.

12. Third Party Materials; Links. The Service may allow access to third-party information, products, services and other materials, including Submissions (collectively, “Third Party Materials”), and including any access via links. We do not control or endorse, and are not responsible for, any Third Party Materials. We have no obligation to monitor Third Party Materials, and we may block or disable access to any Third Party Materials at any time. Your access or use of Third Party Materials is at your own risk and is subject to any additional terms, conditions and policies applicable to such materials.

13. Disclaimer of Warranties. To the fullest extent permitted under applicable law, the Service are made available to you on an “as is,” “where is” and “where available” basis, without any warranties or conditions of any kind, whether express, implied or statutory.

We disclaim all warranties with respect to the Service to the fullest extent permissible under applicable law, including the warranties of non-infringement.

To the fullest extent permissible under applicable law, and subject to any applicable terms and conditions or policies applicable to the use of Third Party Materials as set out in Section 12, Third Party Materials are made available to you on an “as is,” “where is” and “where available basis, without any warranties of any kind, whether express or implied. We disclaim all warranties with respect to Third Party Materials.

Without limiting the generality of the foregoing, to the fullest extent permissible under applicable law, we make no representation or warranty that the Service will be secure, that any user name, password or other security measure that you may use or allow others to use in connection with the Service will prevent unauthorized access to your Service account or related information, or that your Service account or related information will not be accessed or misused by any third party.

All disclaimers of any kind in this Agreement (including in this section and elsewhere in this Agreement) are made for the benefit of the Macitentan REMS, our affiliates and their respective shareholders, stockholders, directors, officers, employees, affiliates, agents, representatives, licensors, suppliers and service providers, and their respective successors and assigns.

While we take reasonable steps to try to maintain the timeliness, integrity and security of the Service, we cannot guarantee that they are or will remain updated, complete, correct or secure, or that access to them will be uninterrupted. The Service may include inaccuracies, errors and materials that conflict with this Agreement. Additionally, third parties may make unauthorized alterations to the Service. If you become aware of any such alteration, please use the link at [Contact Us](#) and provide a description of such alteration and its location on the Service.

14. Limitation of Liability; Indemnification.

Nothing in this Agreement restricts, excludes or modifies or purports to restrict, exclude or modify any mandatory statutory consumer rights under applicable law.

To the fullest extent permitted under applicable law: (a) we will not be liable for any indirect, incidental, consequential, special, exemplary or punitive damages of any kind, or losses that were not reasonably foreseeable to you or us at the time you agreed to this Agreement, in each case arising out of or in connection with the Service or this Agreement, and under any contract, tort (including negligence), strict liability or other theory (collectively, "Indirect Losses"). Loss or damage is foreseeable if either it is obvious that it will happen or if, at the time the contract was made, both you and we knew it might happen.

Without limiting the foregoing, we will not be liable for indirect losses of any kind resulting from your use of or inability to use the Service or from any products or Third Party Materials, including from any Virus that may be transmitted in connection therewith.

We do not exclude or limit in any way our liability to you where it would be unlawful to do so. This includes liability for death or personal injury caused by our negligence or the negligence of our employees, agents or subcontractors, for gross negligence or willful behavior, or for fraud or fraudulent misrepresentation.

All limitations of liability of any kind in this Agreement (including in this section and elsewhere in this Agreement) are made for the benefit of both the Macitentan REMS.

You agree, at your own expense, to defend, indemnify, and hold harmless us, our employees, owners, contractors, officers, directors, agents, affiliated companies, and suppliers, from all liabilities, claims, and expenses, including attorneys' fees, that arise from your (I) alleged acts or omissions, which would constitute a violation of one or more of the terms in this Agreement; and (II) use or misuse of the Site and the Services. We reserve the right to assume control of the defense of any third-party claim that is subject to indemnification by you, in which event you will cooperate with us in asserting any available defenses. Without limiting the foregoing, you may not settle, compromise or in any other manner dispose of any claim without our consent.

15. Third Party Claims. If we are sued by a third party as a result of your breach of this Agreement or your infringement of any Third Party Right, then, to the fullest extent permitted by applicable law, you will be responsible for all liabilities, damages, judgments, awards, losses, costs, expenses and fees (including attorneys' fees) incurred by the Macitentan REMS.

"Third Party Rights" are any right, title, or interest of any person under patent, copyright, trademark or trade secret law or any other statutory provision or common law doctrine relating to property rights.

16. Termination. You may stop using the Service, and thereby terminate this Agreement, at any time. We may terminate or suspend your use of the Service if you do not comply with Macitentan REMS requirements or this Agreement, engage in any fraud or abuse, or if you or anyone using your account makes any misrepresentation to us. Your obligations under this Agreement shall survive any expiration or termination of this Agreement.

17. Governing Law; Jurisdiction. Unless otherwise prescribed by applicable law, this Agreement is governed by and shall be construed in accordance with the laws of the State of New York, without regard to its principles of conflicts of law, and regardless of your location. All disputes between you and us arising out of or related to the Service or this Agreement, whether based in contract, tort, statute, fraud, misrepresentation or any other legal theory and including non-contractual disputes or claims, will be subject to the exclusive jurisdiction of the federal and state courts located in the State of New York, U.S.A., and you waive any jurisdictional, venue or inconvenient forum objections to such courts.

We may assign this Agreement at any time to any subsidiary or any other affiliated company of ours, or as part of the sale to, merger with, or other transfer of our company or any of our company's assets to another entity. We will post a notice on the Site regarding any change of ownership, so you have the opportunity to discontinue your use of the Site or cancel your registration if you do not wish to continue to use the Site and Services under the new ownership. You may not assign this Agreement to anyone else.

18. Filtering. Parental control protections (such as computer hardware, software or filtering services) are commercially available that may assist you in limiting access to material that may be harmful to or inappropriate for minors. Information identifying current providers of such protections (which we do not endorse) is available from https://en.wikipedia.org/wiki/Comparison_of_content-control_software_and_providers.

19. Information or Complaints. If you have a question or complaint regarding the Service, please use the link at [Contact Us](#). California residents may reach the Complaint Assistance Unit of the Division of Consumer Services of the California Department of Consumer Affairs by mail at 1625 North Market Blvd., Sacramento, CA 95834, or by telephone at (916) 445-1254 or (800) 952-5210.

20. Copyright Infringement Claims. If you believe in good faith that materials available on the Service infringe your copyright, you may write to us by mail and request that we remove such material or block access to it. Please be precise about the identity and location of the allegedly infringing materials. If you believe in good faith that someone has wrongly filed a notice of copyright infringement against you, you may send us a written counter-notice. Notices and counter-notices must be sent through the link at [Contact Us](#). This link may also be used to contact us about copyright infringement claims in jurisdictions outside of the United States.

21. Other Important Terms. This Agreement does not, and shall not be construed to, create any partnership, joint venture, employer-employee, agency or franchisor-franchisee relationship between you and us. This Agreement is between you and us. Except as set forth in Section 15, no other person shall have any rights to enforce any of the terms of this Agreement. If any provision of this Agreement is found to be unlawful, void or for any reason unenforceable, that provision will be deemed severable from this Agreement and will not affect the validity and enforceability of any remaining provision. No waiver by either party of any breach or default under this Agreement will be deemed to be a waiver of any preceding or subsequent breach or default. Any heading, caption or section title contained herein is for convenience only, and in no way defines or explains any section or provision. All terms defined in the singular shall have the same meanings when used in the plural, where appropriate and unless otherwise specified. Any use of the term "including" or variations thereof in this Agreement shall be construed as if followed by the phrase "without limitation." This Agreement, our Privacy Policy, and the inclusion of any terms and conditions incorporated herein, is the entire agreement between you and us relating to the subject matter of this Agreement, and, in the absence of fraud, supersedes any and all prior or contemporaneous written or oral agreements or understandings between you and us relating to such subject matter. Notices to you (including notices of changes to this Agreement) may be made via posting to the Service or by e-mail (including in each case via links), or by regular mail. Without limitation, a printed version of this Agreement and of any notice given in electronic form shall be admissible in judicial or administrative proceedings based upon or relating to this Agreement to the same extent and subject to the same conditions as other business documents and records originally generated and maintained in printed form. Neither party will be responsible for any failure to fulfill any obligation due to any cause beyond its control.