



Allergan, plc.
5 Giralda Farms
Madison, NJ 07940
www.Allergan.com
T 800 678 1605

February 20, 2018
Henry Delima

Dear Mr. Delima:

Thank you for your recent request for information concerning VIBERZI (eluxadoline) tablets and VRAYLAR® (cariprazine) capsules and the availability of a Safety Data Sheet (SDS) for Allergan products.

The intention of the enclosed information is to provide you with available data and information from published scientific and medical literature to assist you in your practice decisions. Allergan strives to provide current, accurate, and fair-balanced information that is compliant with current industry guidelines regarding the dissemination of information. Some of this information may address off-label uses that are not approved/licensed/cleared by the U.S. Food and Drug Administration (FDA) or other health agencies. This information is prepared and distributed in response to your unsolicited request and is not to be utilized for the promotion or endorsement for use in unapproved indications as Allergan cannot support any use that is outside the terms of the product license. If you did not request the enclosed materials, please report to Allergan's Medical Information Department.

An SDS does not exist for VIBERZI (eluxadoline) tablets and VRAYLAR® (cariprazine) capsules and therefore we are unable to provide the documentation requested.

The Occupational Safety and Health Administration (OSHA) exempts Safety Data Sheets (SDS) for drugs regulated by the U.S. Food and Drug Administration (FDA) that are in solid final form, including pills or tablets for direct administration to patients. In addition, drug products packaged by the chemical manufacturer intended for sale at a retail establishment to consumers (e.g., over-the-counter drugs) are exempt, as are drug products intended for personal use by employees at their work place (e.g., first aid supplies).¹

The above information is being provided in response to your specific inquiry. Allergan, plc. makes no recommendation regarding unapproved uses. The intention is to provide a synopsis of relevant drug and medical information derived from readily available sources. The information provided may not represent all available information on this topic. Any publication of the provided information or use beyond this intent is prohibited without written authorization from Allergan, plc. As is typical with published scientific and medical literature, some of the information presented in the enclosed or cited references may not conform to the approved labeling for the product(s) mentioned.

Please contact our Medical Information Department at 1-800-678-1605 should you have any further questions. In addition, product prescribing information is available on the web at www.allergan.com.



Allergan, plc.
5 Giralda Farms
Madison, NJ 07940
www.Allergan.com
T 800 678 1605

Thank you for your interest in Allergan, plc. products.

Sincerely,

Allergan Medical Information

All information and personal data that you provide via email will be protected and kept confidential in line with Allergan's Data Protection Policy. All data submitted to Allergan is processed exclusively for the purpose of responding to your enquiry, drug safety surveillance requirements and for internal medical information quality and training purposes. You have a right of access to any personal data that we hold about you.

The attached document(s) has/have been supplied under a Multinational Copyright License protected by copyright and may not (even for internal purposes) be further copied or on-copied electronically without permission, save as may be permitted by law. The recipient may print out a single paper copy of any document received electronically.



Allergan, plc.
5 Giralda Farms
Madison, NJ 07940
www.Allergan.com
T 800 678 1605

Reference:

1. Occupational Safety and Health Standards. Health Communication Statement [Subpart Z, Toxic and Hazardous Substances; 29 CFR 1910.1200(b)(6)(vii)]. Available at:
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10099.
Accessed June 15, 2006.