



Drug recall for Dabigatran Etcxilate Capsules, USP 75 mg and 150 mg

The U.S. Food and Drug Administration (FDA) has announced that Ascend Laboratories LLC is voluntarily recalling one (1) lot of Dabigatran Etcxilate Capsules, USP 75 mg and 150 mg, prescribed as an oral anticoagulant to lower the risk of stroke and blood clots. This drug is being recalled due to the presence of a nitrosamine impurity being above the established Acceptable Daily Intake (ADI) level.

What this means for you:

- To date, the pharmaceutical company has not received any adverse event reports related to this recall.
- It is important that you do not abruptly stop taking your medication without consulting your doctor.
- Talk to your doctor or healthcare provider about switching to another medicine or obtaining the same medicine that is not part of the recall.
- To determine if your medicine is affected, you should look at the drug name and company name on the label of your prescription. If the information is not on the bottle, you should contact the pharmacy that dispensed the medicine.
- Please refer to the Food and Drug Administration website for the most current updates to this drug recall at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ascend-laboratories-llc-issues-voluntary-nationwide-recall-dabigatran-etexilate-capsules-usp-75-mg>
- You can contact Ascend Laboratories LLC with any questions regarding this recall or for instructions on how to return your affected drug by calling **877- 272-7901**, 24 hours a day, 7 days a week.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either by online, regular mail or fax.

- **Online:** Complete and submit the report: <https://www.accessdata.fda.gov/scripts/medwatch/>
 - o Select **Consumer/Patient (FDA Form 3500B)**
- **Regular mail or fax:** Download form at www.fda.gov/media/85598/download
 - o **Form FDA-3500B: Consumer Voluntary Reporting** will automatically download

Note: A reporting form also may be requested by calling **800-332-1088 (TTY:711)**. Complete and return to the address on the pre-addressed form, or submit by fax to **800-FDA-0178**.

If you have questions about this medicine or the recall, please talk to your doctor or pharmacist. You may also call the number on the back of your Humana member ID card.

For 24-hour service, you can sign into MyHumana, your personal, secure online account on Humana.com, to search for other medicine that your plan covers.

As your partner in health, we want to make sure that you are informed about issues that may affect your health and overall well-being.



Important

At Humana, it is important you are treated fairly.

Humana Inc. and its subsidiaries do not discriminate or exclude people because of their race, color, national origin, age, disability, sex, sexual orientation, gender, gender identity, ancestry, ethnicity, marital status, religion, or language. Discrimination is against the law. Humana and its subsidiaries comply with applicable Federal Civil Rights laws. If you believe that you have been discriminated against by Humana or its subsidiaries, there are ways to get help.

- You may file a complaint, also known as a grievance:
Discrimination Grievances, P.O. Box 14618, Lexington, KY 40512-4618
If you need help filing a grievance, call **877-320-1235** or if you use a **TTY**, call **711**.
- You can also file a civil rights complaint with the **U.S. Department of Health and Human Services**, Office for Civil Rights electronically through their Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or at **U.S. Department of Health and Human Services**, 200 Independence Avenue, SW, Room 509F, HHH Building, Washington, DC 20201, **800-368-1019**, **800-537-7697 (TDD)**. Complaint forms are available at <https://www.hhs.gov/ocr/office/file/index.html>.
- **California residents:** You may also call California Department of Insurance toll-free hotline number: **800-927-HELP (4357)**, to file a grievance.

Auxiliary aids and services, free of charge, are available to you. 877-320-1235 (TTY: 711)

Humana provides free auxiliary aids and services, such as qualified sign language interpreters, video remote interpretation, and written information in other formats to people with disabilities when such auxiliary aids and services are necessary to ensure an equal opportunity to participate.

Language assistance services, free of charge, are available to you. 877-320-1235 (TTY: 711)

Español (Spanish): Llame al número arriba indicado para recibir servicios gratuitos de asistencia lingüística.

繁體中文 (Chinese): 撥打上面的電話號碼即可獲得免費語言援助服務。

Tiếng Việt (Vietnamese): Xin gọi số điện thoại trên đây để nhận được các dịch vụ hỗ trợ ngôn ngữ miễn phí.

한국어 (Korean): 무료 언어 지원 서비스를 받으려면 위의 번호로 전화하십시오.

Tagalog (Tagalog – Filipino): Tawagan ang numero sa itaas upang makatanggap ng mga serbisyo ng tulong sa wika nang walang bayad.

Русский (Russian): Позвоните по номеру, указанному выше, чтобы получить бесплатные услуги перевода.

Kreyòl Ayisyen (French Creole): Rele nimewo ki pi wo la a, pou resevwa sèvis èd pou lang ki gratis.

Français (French): Appelez le numéro ci-dessus pour recevoir gratuitement des services d'aide linguistique.

Polski (Polish): Aby skorzystać z bezpłatnej pomocy językowej, proszę zadzwonić pod wyżej podany numer.

Português (Portuguese): Ligue para o número acima indicado para receber serviços linguísticos, grátis.

Italiano (Italian): Chiamare il numero sopra per ricevere servizi di assistenza linguistica gratuiti.

Deutsch (German): Wählen Sie die oben angegebene Nummer, um kostenlose sprachliche Hilfsdienstleistungen zu erhalten.

日本語 (Japanese): 無料の言語支援サービスをご要望の場合は、上記の番号までお電話ください。

فارسی (Farsi)

برای دریافت تسهیلات زبانی بصورت رایگان با شماره فوق تماس بگیرید.

Diné Bizaad (Navajo): Wóda'í béésh bee hani'í bee wolta'ígíí bich'í' hódíílnih éí bee t'áá jiik'eh saad bee áká'ánída'áwo'déé nika'adoowoł.

العربية (Arabic)

GCHJV5REN 0721

الرجاء الاتصال بالرقم المبين أعلاه للحصول على خدمات مجانية للمساعدة بلغتك