

# IMPORTANT DABIGATRAN ETEXILATE CAPSULES, USP 75 MG AND 150 MG. RECALL NOTICE

## Dear Member,

Your health is important to us. On March 22, 2023 the U.S. Food and Drug Administration (FDA) announced a drug recall notice. It is for specific lots of Ascend Laboratories **Dabigatran Etexilate Capsules**, **USP 75 mg and 150 mg.**<sup>1</sup> The FDA issued the recall because the product may have a safety concern.

# Products that may be affected by this recall:

Product	NDC	Lot Number	Expiration Date	Configuration /Count
Dabigatran Etexilate Mesylate Caps 150 Mg	67877-475-60	22142448	MAY.2024	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 150 Mg	67877-475-60	22142449	MAY.2024	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 150 Mg	67877-475-60	22142450	MAY.2024	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22142462	MAY.2024	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22142463	MAY.2024	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22142464	MAY.2024	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22143000	JUN.2024	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22143001	JUN.2024	60 capsules/bottle

Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22143002	JUN.2024	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 150 Mg	67877-475-60	22143845	JUL.2024	60 capsules/bottle

Additional information is available at: <a href="https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ascend-laboratories-llc-issues-voluntary-nationwide-recall-dabigatran-etexilate-capsules-usp-75-mg?utm\_medium=email&utm\_source=govdelivery</a>

Please call your pharmacy to find out if your drug could be part of this recall. The pharmacy may replace the drug. We are writing this letter to give you information. This should not replace your doctor's advice. Only your doctor can decide what drugs are right for you.

Please disregard this letter if you are not currently taking **Dabigatran Etexilate Capsules**, **USP 75 mg and 150 mg** or if this safety warning does not apply to you. Our records may not be complete, or your doctor may have discontinued this medication.

Sincerely,

#### Doctors HealthCare Plans, Inc.

ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 786-460-3427 o 833-342-7463(TTY: 711).

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1. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ascend-laboratories-llc-issues-voluntary-nationwide-recall-dabigatran-etexilate-capsules-usp-75-mg?utm\_medium=email&utm\_source=govdelivery

#### DISCRIMINATION IS AGAINST THE LAW

Doctors HealthCare Plans, Inc. complies with applicable civil rights laws and does not discriminate or exclude individuals on the basis of race, color, national origin, age disability, sex, sexual orientation, pregnancy, gender, gender identity, or religion.

Doctors HealthCare Plans, Inc. provides: (1) free aids and services to people with disabilities to communicate effectively with us, such as, qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats); and, (2) free language services to individuals whose primary language is not English, such as, qualified interpreters and information written in other languages.

If you need these services, contact the number on the back of your ID Card. If you believe that Doctors HealthCare Plans, Inc., has failed to provide these services or discriminated in any way, you can file a grievance with: **Doctors HealthCare Plans, Inc.**, Attention: Member Services Department, 2020 Ponce de Leon Blvd., PH 1, Coral Gables, FL 33134 or call (786) 460-3427 or (833) 342-7463, TTY:711; 7 days a week; 8AM to 8PM EST.

You can file a grievance by calling, in person or by mail. If you need help filing a grievance, our Member Services Representatives are available to help you at the number listed above. You can also file a civil rights complaint electronically through the U.S. Department of Health and Human Services, Office for Civil Rights Complaint Portal, available at <a href="https://ocrportal.hhs.gov/ocr/portal/lobby.jsf">https://ocrportal.hhs.gov/ocr/portal/lobby.jsf</a>, or by mail or phone at: **U.S. Department of Health and Human Services**, 200 Independence Avenue, SW, Room 509F, HHH Building, Washington, D.C. 20201 or call (800) 368-1019, (800) 537-7697 (TDD). Complaint forms are available at <a href="http://www.hhs.gov/ocr/office/file/index.html">http://www.hhs.gov/ocr/office/file/index.html</a>.

#### MULTI-LANGUAGE INTERPRETER SERVICE

**English:** We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at (833) 342-7463 (TTY:711). Someone who speaks English/Language can help you. This is a free service.

**Spanish:** Tenemos servicios de intérprete sin costo alguno para responder cualquier pregunta que pueda tener sobre nuestro plan de salud o medicamentos. Para hablar con un intérprete, por favor llame al (833) 342-7463 (TTY:711). Alguien que hable español le podrá ayudar. Este es un servicio gratuito.

Chinese Mandarin: 我们提供免费的翻译服务,帮助您解答关于健康或药物保险的任何疑问。如果您需要此翻译服务,请致电 (833) 342-7463 (TTY:711)。我们的中文工作人员很乐意帮助您。这是一项免费服务。

Chinese Cantonese: 您對我們的健康或藥物保險可能存有疑問,為此我們提供免費的翻譯服務。如需翻譯服務,請致電 (833) 342-7463 (TTY:711)。我們講中文的人員將樂意為您提供幫助。這是一項免費服務。

**Tagalog:** Mayroon kaming libreng serbisyo sa pagsasaling-wika upang masagot ang anumang mga katanungan ninyo hinggil sa aming planong pangkalusugan o panggamot. Upang makakuha ng tagasaling-wika, tawagan lamang kami sa (833) 342-7463 (TTY:711). Maaari kayong tulungan ng isang nakakapagsalita ng Tagalog. Ito ay libreng serbisyo.

**French:** Nous proposons des services gratuits d'interprétation pour répondre à toutes vos questions relatives à notre régime de santé ou d'assurance-médicaments. Pour accéder au service d'interprétation, il vous suffit de nous appeler au (833) 342-7463 (TTY:711). Un interlocuteur parlant Français pourra vous aider. Ce service est gratuit.

**Vietnamese:** Chúng tôi có dịch vụ thông dịch miễn phí để trả lời các câu hỏi về chương sức khỏe và chương trình thuốc men. Nếu quí vị cần thông dịch viên xin gọi (833) 342-7463 (TTY:711) sẽ có nhân viên nói tiếng Việt giúp đỡ quí vi. Đây là dịch vu miễn phí.

**German:** Unser kostenloser Dolmetscherservice beantwortet Ihren Fragen zu unserem Gesundheits- und Arzneimittelplan. Unsere Dolmetscher erreichen Sie unter (833) 342-7463 (TTY:711). Man wird Ihnen dort auf Deutsch weiterhelfen. Dieser Service ist kostenlos.

**Korean:** 당사는 의료 보험 또는 약품 보험에 관한 질문에 답해 드리고자 무료 통역 서비스를 제공하고 있습니다. 통역 서비스를 이용하려면 전화 (833) 342-7463 (TTY:711) 번으로 문의해 주십시오. 한국어를 하는 담당자가 도와 드릴 것입니다. 이 서비스는 무료로 운영됩니다.

**Russian:** Если у вас возникнут вопросы относительно страхового или медикаментного плана, вы можете воспользоваться нашими бесплатными услугами переводчиков. Чтобы воспользоваться услугами переводчика, позвоните нам по телефону (833) 342-7463 (ТТҮ:711). Вам окажет помощь сотрудник, который говорит по-русски. Данная услуга бесплатная.

### Arabic:

إننا نقدم خدمات المترجم الفوري المجانية للإجابة عن أي أسئلة تتعلق بالصحة أو جدول الأدوية لدينا. للحصول على مترجم فوري، ليس عليك سوى الاتصال بنا على (TTY:711) 342-7463 (833). سيقوم شخص بمساعدتك. هذه خدمة مجانية ما يتحدث العربية

**Italian:** È disponibile un servizio di interpretariato gratuito per rispondere a eventuali domande sul nostro piano sanitario e farmaceutico. Per un interprete, contattare il numero (833) 342-7463 (TTY:711). Un nostro incaricato che parla Italianovi fornirà l'assistenza necessaria. È un servizio gratuito.

**Portugués:** Dispomos de serviços de interpretação gratuitos para responder a qualquer questão que tenha acerca do nosso plano de saúde ou de medicação. Para obter um intérprete, contacte-nos através do número (833) 342-7463 (TTY:711). Irá encontrar alguém que fale oidioma Português para o ajudar. Este serviço é gratuito.

**French Creole:** Nou genyen sèvis entèprèt gratis pou reponn tout kesyon ou ta genyen konsènan plan medikal oswa dwòg nou an. Pou jwenn yon entèprèt, jis rele nou nan (833) 342-7463 (TTY:711). Yon moun ki pale Kreyòl kapab ede w. Sa a se yon sèvis ki gratis.

**Polish:** Umożliwiamy bezpłatne skorzystanie z usług tłumacza ustnego, który pomoże w uzyskaniu odpowiedzi na temat planu zdrowotnego lub dawkowania leków. Aby skorzystać z pomocy tłumacza znającego język polski, należy zadzwonić pod numer (833) 342-7463 (TTY:711). Ta usługa jest bezpłatna.

Hindi: हमारे सवा य या दवा की योजना के बारे मों आपके किसी भी परन के जवाब देने के लिए हमारे पास मुफत दुभाषिया सेवाएँ उपलब्ध हैं. एक दुभाषिया परापत करने के लिए, बस हमों (833) 342-7463 (TTY:711) पर फोन करें. कोई व्यक्त जो हिन्दी बोलता है आपकी मदद कर सकता है. यह एक मुफ्त सेवा है.

Japanese: 当社の健康健康保険と薬品 処方薬プランに関するご質問にお答えするために、無料の通訳サービスがありますございます。通訳をご用命になるには、(833) 342-7463 (TTY:711) にお電話ください。日本語を話す人者が支援いたします。これは無料のサービスです。